THE ROLE OF DUTASTERIDE IN REDUCING THE COMPLICATIONS OF TRANSURETHRAL RESECTION OF PROSTATE

Dissertation submitted to

THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY

In partial fulfilment of the requirements for

the award of the degree of

M.Ch (UROLOGY) – BRANCH – IV

THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY

CHENNAI

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DECLARATION

I solemnly declare that this dissertation titled "THE ROLE OF DUTASTERIDE IN REDUCING THE COMPLICATIONS OF TRANSURETHRAL RESECTION OF PROSTATE" was prepared by me in the Department of Urology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai under the guidance and able supervision of Prof. R. Jeyaraman MS, M.Ch., Professor & Head of the Department, Department of Urology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai. This dissertation is submitted to the Tamil Nadu Dr. MGR Medical University, Chennai in partial fulfilment of the university requirements for the award of the degree of M.Ch. Urology.

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CERTIFICATE

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INTRODUCTION

Prostate is one of the major accessory sex gland of male reproductive system. The prostate is a pyramidal shaped fibromuscular glandular organ and it surrounds the prostatic urethra from the bladder base to the external urethral sphincter.The prostate was initially divided into five anatomical lobes in fetal life before the 20 weeks of gestation and it has anterior,posterior,2 lateral and middle lobe [2].In normal adult male only three lobes are present which includes two lateral lobes which can be palpated via the rectum and a median lobe which projects normally into the urethra raising a prominence on its floor and produce crista urethralis or verumontanum.

Prostate has exocrine functions and doubtful endocrine function.Prostate secretes about 0.5 ml of the total 3ml seminal fluid.It produce many important secretory proteins like prostate specific antigen (PSA) and acid phosphataset[(3)].These two proteins are very useful in patients with carcinoma prostate evaluations.

As the age increases prostate continue to enlarge in size under the influence of dihydrotestosterone and testosterone. Enlargement of the prostate can lead to bladder outlet obstruction and produce lower urinary tract symptoms(LUTS). Because of the its age dependent illness, the exact prevalence and incidence of BPH cannot be quantified.BPH prevalence is

greater than 50% by the 6^{th} decade and by the 8^{th} decade BPH prevalence is as high as 90%.As the age increases, bother some symptoms also tends to increase with age and affects the quality of life.Prostate enlargement in old age was mentioned by various names which include benign prostatic hyperplasia (BPH), benign prostatic enlargement (BPE), or benign prostatic obstruction (BPO), benign prostatic hypertrophy, etc. Prostate enlargement produce wide variety of symptoms which are known as lower urinary tract symptoms.They can be classified as obstructive and irritative symptoms and also known as voiding and storage symptoms respectively.It includes hesitancy, thin stream, intermittency, post void dribble, decreased force of urination, straining, nocturia, frequency and dysuria.

LUTS are not only caused by benign prostatic enlargement and also caused by wide variety of diseases.Hence,the complete evaluation of patients with LUTS should include the detailed history, clinical examination, per rectal examination followed by ultrasound, subjective assessment of symptoms in the form of various questionnaires(IPSS), uroflowmetry and invasive pressure flow studies.

Management of the patients diagnosed with enlarged prostate due to benign prostatic hyperplasia depends on symptom of the patient and the complications of BPH.Absolute indications for the intervention in BPH are

recurrent infection,acute urinary retention,recurrent hematuria and azotemia.Various options available for the management include are watchful waiting, medical management with alpha blockers or 5 alpha reductase inhibitors and various minimally invasive and endoscopic procedures like TURP, Transurethral needle ablation of prostate (TUNA), transurethral ultrasound–guided laser-induced prostatectomy (TULIP), transurethral vaporization of the prostate (TUVP), transurethral incision of prostate (TUIP) and open prostatectomy.

In the modern era of endoscopic field the need for open procedure becomes less and less but still it has some indications like larger prostate more than 75 grams, BPH with large bladder diverticulum and associated large vesical stone, and conditions not suitable for the lithotomy position like ankylosis of hip joint.Among the endoscopic procedure TURP is the “gold standard” treatment and most commonly performed surgical procedure for benign prostatic hyperplasia. Bleeding is one of the most important intra operative and post operative complication in TURP.The amount of intraoperative bleeding depends on the volume of the prostate gland,duration of the surgical procedure and the surgeon’s technique. The bleeding from the artery can be controlled by electrocoagulation and the perioperative blood loss cause haemodynamic instability and cause very much anxiety to the patient and its relatives.Post TURP bleeding can leads onto clot retention,urinary tract infection and increased the duration of hospital stay.

Since the development of prostate is dependent on the dihydrotestosterone,androgen suppressive therapy[4] can be used as the medical therapy for BPH.Testosterone conversion into dihydrotestosterone(DHT) is inhibited by the 5alpha reductase inhibitors like Finasteride and Dutasteride.These drugs will inhibit the prostate growth.Hematuria will occur in BPH depends on the microvessel density in the prostatic urothelium.Several studies showed that finasteride prevents recurrent gross hematuria in BPH[6] .Some research studies suggest that the androgen controlled vascular endothelial growth factor^2 is suppressed by finasteride and leads on to decreased angiogenesis.The finasteride inhibits only type2 5alpha reductase and the dutasteride inhibits both type1and type2 isoenzymes.So,if finasteride decreases TURP bleeding complication,dutasteride also can decrease the bleeding complication of TURP[36].

AIM AND OBJECTIVE

The primary aim and objective of the present study is to determine whether preoperative treatment with Dutasteride decreases surgical blood loss in patients who undergo transurethral resection of the prostate for benign prostatic hyperplasia with prostate >30cc volume with acute urinary retention. The secondary objective is to assess the postoperative complication like clot retention,blood transfusion,failure to void after the catheter removal and the urinary tract infection in post operative period.

REVIEW OF LITERATURE

Benign prostatic hyperplasia is the common abnormality in more than 50 years of age in men. Enlargement of the prostate occurs as the male becomes aged and cause urinary tract symptoms.Medical and surgical options are available for the treatment of benign prostatic hyperplasia.Eventhough various endoscopic procedures are available for BPH, TURP is the 'gold standard' against which all other newer modalities are compared.

PROSTATE

EMBRYOLOGY OF PROSTATE;

Prostate develops as a derivative of primitive endoderm during 10^{th} week of intrauterine life. It develops distal to the bladder neck via the proliferation of epithelial buds extending out from the urogenital sinus epithelium.Prostate buds invade at stereotyped location that pattern the future development of distinct prostate lobes in the rodent and zones in the human.

1)Induction of prostate budding

The androgen receptor signalling machinery is present throughout the lower genitourinary tract.But prostate epithelial buds form at precise location by homeobox(HOX) genes which are transcriptional regulators that govern differential gene expression along the craniocaudal and proximal distal axes in the genitourinary tract.

2)Mesenchymal Condensation

It is mediated by gene for Noggin,Bone morphogenic protein(BMP) signalling which enhances mesenchymal condensation.Condensed mesenchyme has more expression of FGF which is essential for epithelial bud outgrowth.

By this process the urogenital sinus mesenchymal cells become closely packed together.It is an androgen independent and occurs in both male & female.

3)Epithelial Budding

Epithelial expression of the NK homeobox transcription family member Nkx 3.1 is earliest indicator of prostate development at the molecular level[51].It is an androgen dependent process.Prostate budding needs intricate epithelial-mesenchymal interactions.Androgens presence alone is not important for the development but it should also present in sufficient quantity to continue the prostatic differentiation in embryo.

ANATOMY

Prostate is pyramidal shaped gland located at the neck of the bladder and it surrounds the entire prostatic urethra.It is fibro muscular gland and lies behind the symphysis pubis. It measures about 3cm in length and 4cm in width and 2cm in depth(size & shape of a chestnut). Prostate weighs about 14 to18gm in normal adult male and its weight increases as the age increases.

Prostatet has no true fibrous capsule which is formed by visceral layer of pelvic fascia.The false capsule(surgical) is formed around an area of adenoma by a condensation of prostatic tissue which is pushed to the periphery of gland. Prostate is enclosed by visceral fascia which contains the neurovascular tissue. This capsule contain collagen, elastin, and more amount of smooth muscle.It is firmly adherent to the gland and forms numerous fibro muscular septa which divide the prostate glands into indistinct lobules. It is attached to pubis by puboprostatic ligament anteriorly and the urogenital diaphragm supports the inferior part of prostate. Prostate is traversed by urethra and posteriorly perforated by ejaculatory ducts, and it contains the prostatic utricle.

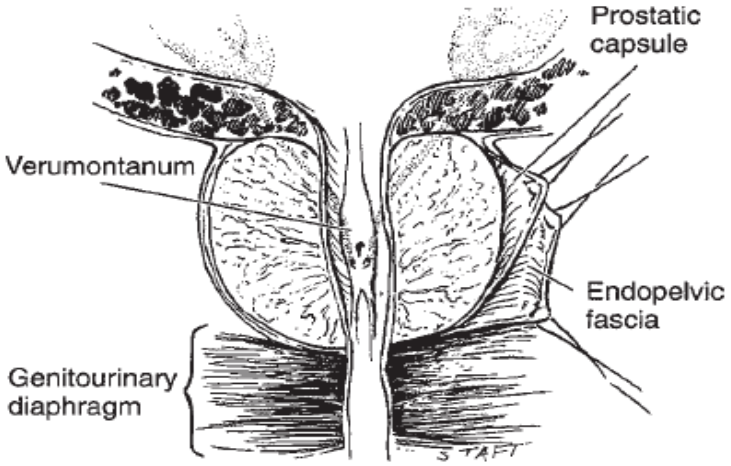


Figure 1. Cut Section of Prostate

Prostate contains 70% glandular elements and 30% fibro muscular stroma. It is made up of tubuloalveolar gland type.

Lowsley classified the prostate into 5 lobes which are anterior lobe, posterior lobe and median lobe which project into bladder when it enlarged and right&left lateral lobes which are situated on both sides of the urethra. Franks divided the prostatic tissue with an inner (urethral) and outer glandular configuration.

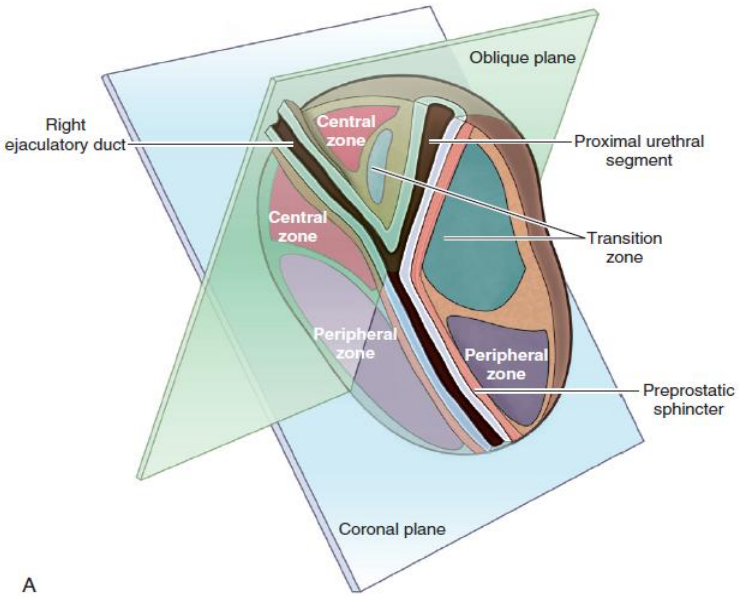


Figure 2. Zonal anatomy of prostate – coronal plane.

McNeal and Lowsley proposed that the inner urethral glands should be considered separately from the prostate and its intrinsic architecture.

According to J.E McNeal(1978), the urethra separates the prostate tissue into ventral or anterior part (fibromuscular) and dorsal or posterior part

(glandular). McNeal divided the prostate into four zones : peripheral zone, central zone, transition zone, and periurethral gland region.

Prostate zones[51] are distinguished by,

1)Their duct location in the urethra

2)Diseases developed from the zone

3)By their embryologic origin

These prostatic zones can be seen clearly with transrectal ultrasound.

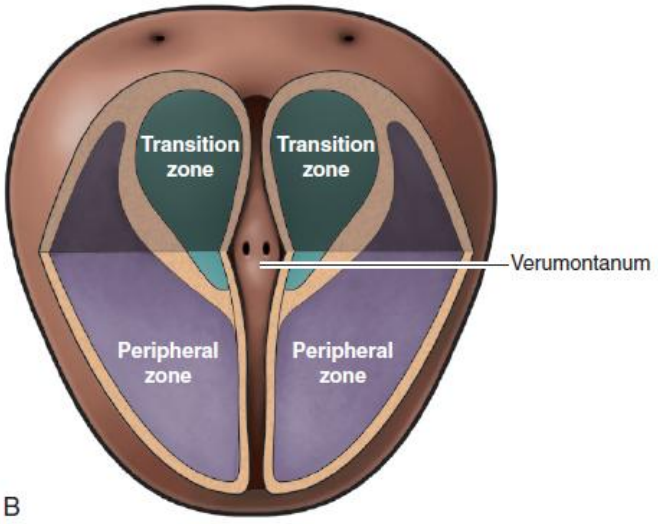


Figure 3.Zonal anatomy of prostate – sagittal plane.

Central zone of prostate arise from Wolffian duct and other zones are arise from urogenital sinus. BPH commonly occurs in transitional zone and 70% of malignancy& inflammation of prostate develops from the peripheral zone. The central zone surrounds the ejaculatory duct and peripheral zone is cup-shaped and it encloses the central transitional zone and also the

preprostatic urethra except anteriorly.Adenocarcinoma of prostate can also arise from the transition zone about 20%.The central zone is rarely involved in any disease.

Prostate derives it blood supply through the inferior vesical, internal pudendal, and middle rectal arteries. Inferior vesical artery divides into urethral and capsular branches.Urethral artery reach the bladder neck at 1 to 5 o'clock and 7 to 11 o'clock position[7] which is important during TURP and open surgical procedure.Capsular branches runs posterolateral to the prostate in the neurovascular bundle. Prostate is drained by peri prostatic plexus which further drains into deep dorsal vein of penis and internal iliac veins.Prostate lymphatic drainage is by internal iliac, sacral and obturator nodes.

BENIGN PROSTATIC HYPERPLASIA

HISTORY

Urinary obstruction due to prostatic enlargement was described even in the olden days of medicine. The relationship between BPH and urinary outlet obstruction initially proposed by Riolan as early as 17th century and further descibed by Morgagni in mid- 18th century. Morgagni proposed the one of the earliest descriptions of BPH . Virchow identified the specific pathologic process in 19th century. Even after the understanding the pathologic process exact cause BPH remains elusive.

AETIOPATHOGENESIS

Benign Prostatic Hyperplasia is defined as “histological enlargement of the prostate gland from progressive hyperplasia of stromal and glandular prostatic cells”. Such a hyperplasia begin in the part of urethra which is surrounded by prostate because increased number of glandular elements in the above mentioned area.

Growth of the tissue occur from proliferation of the fibroblast or myofibroblast and epithelial glandular elements. Gland formation is usually occur only during gestational life. But this process of gland formation once again started in enlarging prostate gland is indicate that reawakening of inductive potential which usually only seen during fetal development.

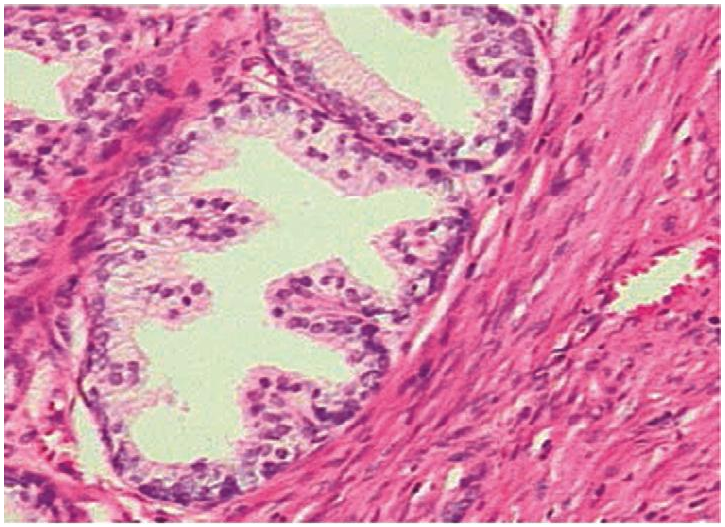


Figure 4. Stromoglandular hyperplasia

Aetiology of this process is not known . The process of hyperplasia occurs in multifocal manner and it exhibits variegated histology mixed with different ratios of stromal nodular and glandular hyperplastic areas.

Factors important in aetiology are,

1. Androgens,
2. Oestrogens,
3. Stromal-epithelial interactions,
4. Regulation of Programmed Cell Death
5. Neurotransmitters
6. Growth Factors

HORMONAL FACTORS

Hormonal factors such as androgens and oestrogens are playing a role in the prostate enlargement**.** The prostate development requires testicular androgens like testosterone and dihydrotestosterone (DHT). Androgens are required not only for proliferation and differentiation but also important for actively inhibiting the cell death**.**

Enzyme 5alpha-reductase which converts the hormone testosterone into DHT, which is the most potent and active androgen in prostatic tissue because

of its increased affinity for androgen receptor(AR). Binding of androgen to AR leads to receptor activation and which in turn bound with particular DNA sites in the nucleus which results in increased transcription of androgen dependent genes resulting in protein synthesis. Castrations before puberty and other gene factors that reduce androgen production resulting in failure of development of BPH. Androgen withdrawal in established BPH leads to reduction in the size of BPH[6]. Androgen withdrawal exert its effect by vascular effects, inactivation of important androgen dependent genes like PSA and also by activation of important genes involved in programmed cell death.

Another hormone Oestrogen also has an unclear role as compared to its role in dogs where it has a role in pathogenesis of benign enlargement.

APOPTOSIS

It is also known as programmed cell death. Apoptosis is a mechanism important for the normal physiological maintenance of glandular homeostasis. It occurs without activation of immune mechanism. It needs RNA and protein synthesis. Following castration, active cell death is more in luminal epithelium and also in distal part of prostatic ducts. TNF-β family of cytokines needed for this process.

EMBRYONIC REAWAKENING THEORY

Paracrine type of communication is present between the stroma and epithelium. Stromal component defect leads to failure of normal braking mechanism and failure of normal cellular proliferation inhibition. This type of new gland occurrence in the hyperplastic prostate indicates a “reawakening” of embryonic processes in which underlying prostatic stroma induces epithelial cell development[51].

GROWTH FACTORS (GF)

These are proteins made of peptides that stimulate, or inhibit the cell division and differentiation processes**.** Cells that respond to growth factors have on their responding cells and cell surface receptors are specific for that particular growth factor. Receptor in turn connected to a variety of trans membrane and intracellular signalling mechanisms. Lawson's team was the first to explain that extracts of BPH will increase the cellular growth. Later date this factor is identified as basic fibroblastic growth factor (b-FGF). Stimulatory growth factors includes,

1. Basic fibroblast growth factors
2. Acidic fibroblast growth factors
3. Integrin-2
4. Epidermal GF
5. Vascular endothelial growth factor (VEGF)

6. Keratinocyte GF
7. Insulin-like GF

Inhibitory factors,

1. Transforming growth factor-β - Down regulated in hyperplasia

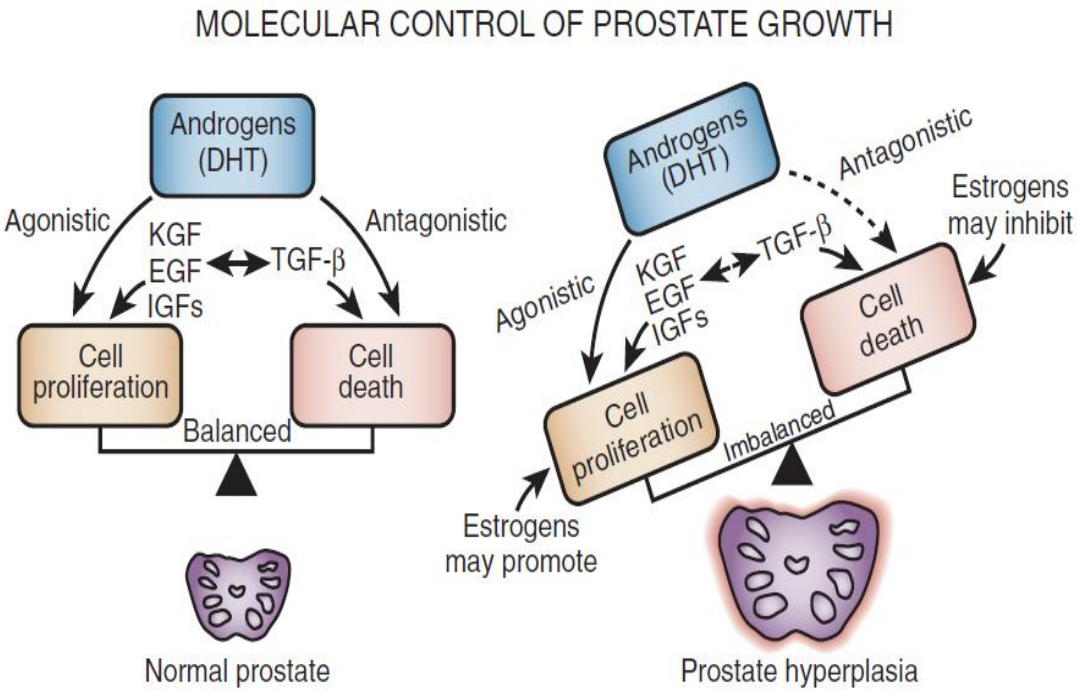


Figure 5 : Molecular control mechanisms involved in the development of hyperplasia

Inflammatory cell will produce these type of growth factors. Theyer and associates found increased number of inflammatory T cells in prostatic tissue of patients with BPH.

OTHER SIGNALLING PATHWAYS

Sympathetic signalling pathways also has some role in the pathophysiology of BPH. Evidence showed that blockade of alpha recepter in some model systems can induce apoptosis. Renin-angiotensin system also are present in prostatic tissue and may be stimulated in BPH.

PATHOLOGY OF BPH

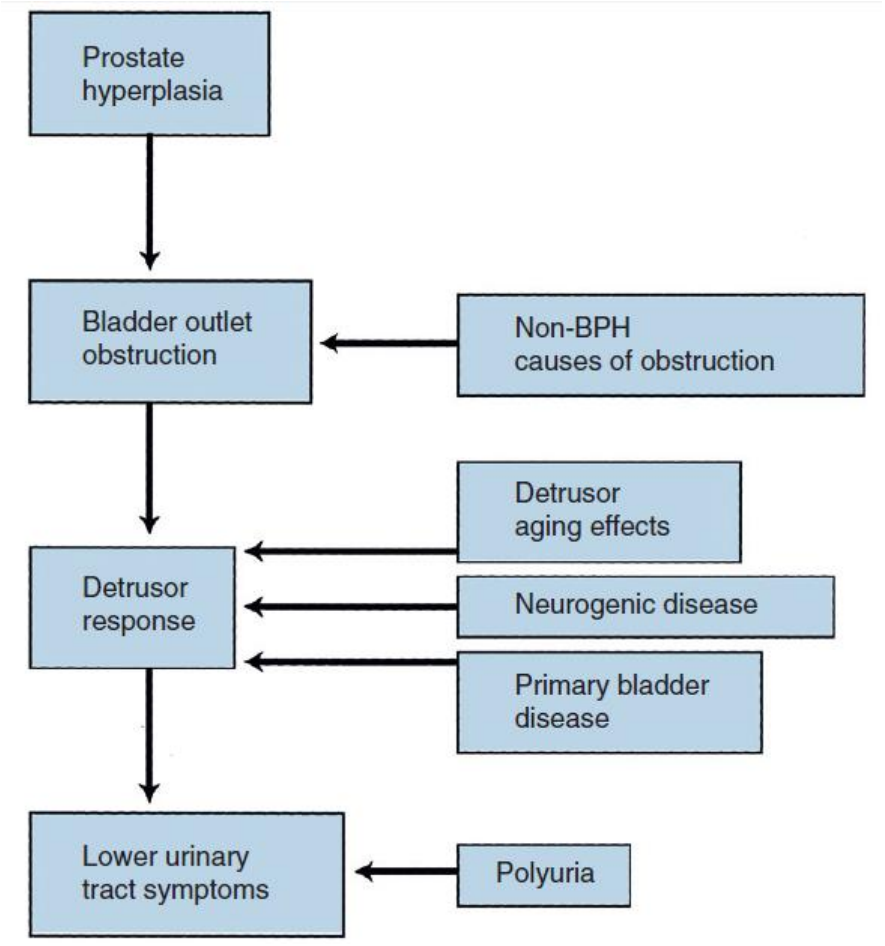


Figure 6 : Pathophysiology of benign prostatic hyperplasia

Hyperplasia usually occurs in the periurethral transition zone of prostate. When there is imbalance between death and proliferation of epithelial and stromal cells,it will leads to enlargement of the prostate gland. It is characterised by proliferation of glandular tissue which is the earliest change with minimal alteration of stromal elements.

Marked variability is present in stromal-epithelial ratios, such as small glands have predominant fibro muscular stroma and large glands demonstrate mainly epithelial nodules. Smooth muscles also has some important role in pathophysiology of BPH.

From the autopsy studies, Barry and colleagues described that BPH is a gradually progressive disease which commences in men in their 40 years of age. Baltimore Longitudinal Study of Aging suggests the progressive nature of the enlarged prostate in aging males. The prostate volume increase by about 0.6 ml per year.Due to prostate enlargement,the mean fall in flow rate is about 0.2 ml/s/year.

SYMPTOMS

Prostate enlargement will produce wide variety of symptoms which are known as lower urinary tract symptoms and they can classified as obstructive and irritative. They can be called as voiding and storage symptoms

respectively. The term lower urinary tract symptom (LUTS) [51] was coined by Paul Adams.

OBSTRUCTIVE SYMPTOMS

1. Hesitancy,
2. Thin stream,
3. Intermittency,
4. Post void dribble,
5. Decreased force of urination
6. Straining

IRRITATIVE SYMPTOMS

1. Nocturia
2. Frequency
3. Dysuria

EVALUATION OF BPH

Symptoms are the important factor to decide about the management of BPH, hence complete evaluation and the subjective assessment of the symptoms should be done. It begins with detailed history with complete and systematic examination including detailed per rectal examination (DRE) and focussed neurological examination.Complete urine analysis, culture and sensitivity and assessment of renal functions should be done.

ULTRASOUND

It can be done through either trans abdominal or transrectal,but trans abdominal USG is commonly done.Trans abdominal USG uses 3.5 MHz probe and high frequency 7-10 MHz probes for Trans rectal ultrasound. Volume of prostate calculated by depending on the shape of the prostate like if prostate is ellipse ($\pi/6$ × transverse diameter × AP diameter × longitudinal diameter), sphere ($\pi/6$ × transverse diameter3), or a prelate (egg-shaped) spheroid ($\pi/6$ × transverse diameter2 × AP diameter). Post void residual(PVR) urine is also measured in BPH evalution.

Post void residual(PVR) Urine Volume

It is known as amount of fluid remaining in the bladder immediately after the urination.The normal PVR can varies from 0.09ml to 2.24ml(mean;0.53ml).But in general,78% of normal men have PVR <5ml and 100% have volume of <12ml.Post void residual urine volume is particularly useful for men on conservative treatment for BPH and they should be monitored closely & regularly.

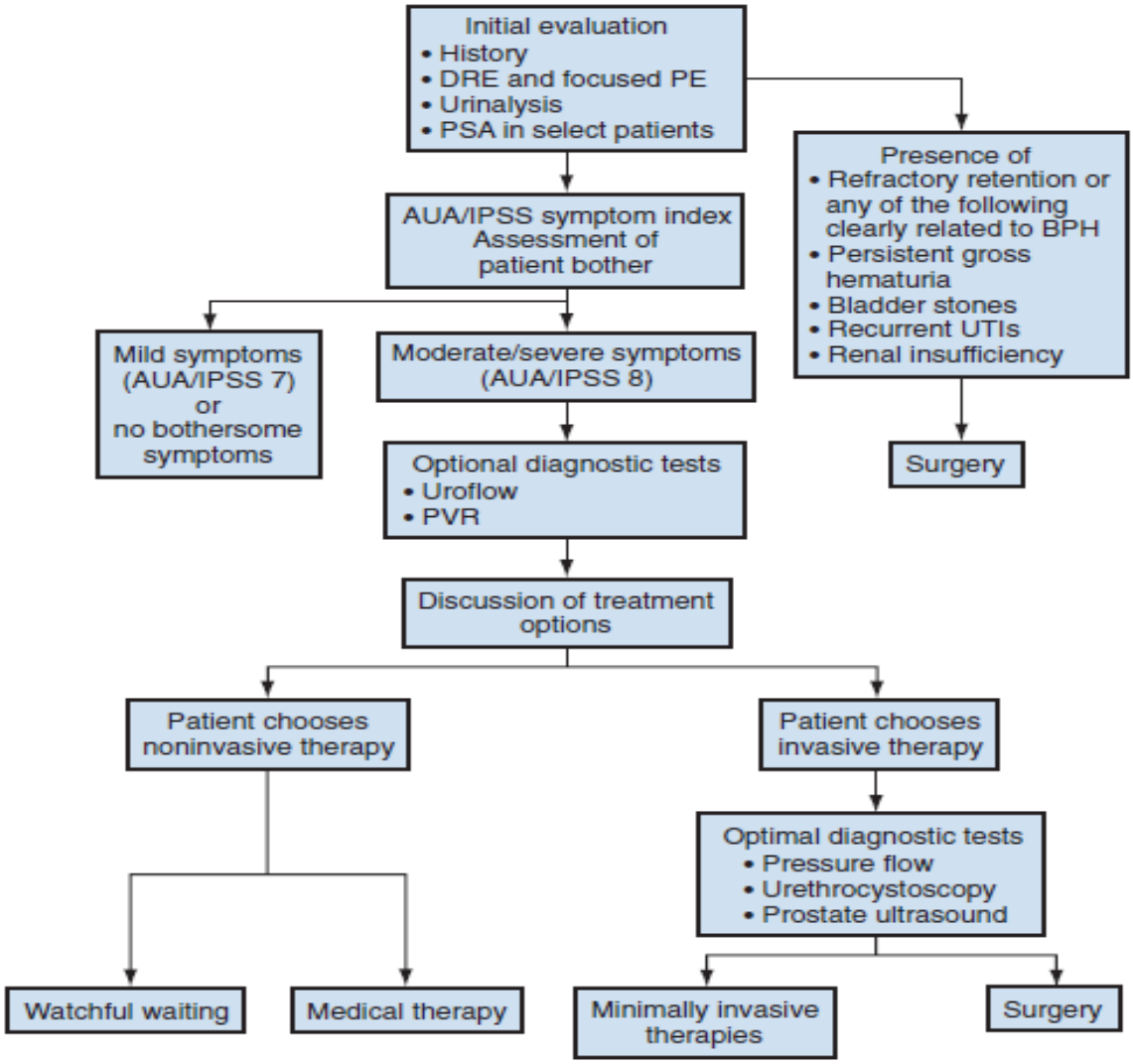
Upper urinary tract imaging is only recommended in,

1. Patients presenting with haematuria,
2. Associated or suspected urinary tract infection,
3. Elevated renal parameters
4. History of renal stones

5. Previous genito - urinary tract surgery.

In the above conditions patient may need a computerized tomography for the complete evaluation. Serum PSA (Prostate Specific Antigen) is done in patients with the family history of prostate cancer and suspected DRE-nodular& hard prostate enlargement.The International ProstateSymptom Score(IPSS) is most commonly used for the symptoms assessment in benign prostatic hyperplasia. This scoring system is also useful for evaluating patients present with LUTS. In addition to the IPSS ,objective assessment is done with uroflowmetry which asses the urinary flow rate. The peak flow, mean flow and voiding times of the patient are measured by uroflowmetry test. Even though urodynamic studies are considered as gold standard test for evaluating the patients with LUTS they are not routinely done for all BPH patients.

Figure 7 : Guideline algorithm for Evaluation of benign prostatic hyperplasia.



Urodynamic studies may be indicated in following situations, (EAU 2012)

a. cannot void > 150 mL;
b. When Qmax is less than 15 ml/second,
c. Age less than 50years or more than 80years,
d. Patients with more than 300 ml of residual urine ,
e. Suspicion of neurological bladder dysfunction,
f. Patients with both side hydronephrosis,
g. Previous radical surgery in pelvis,
h. Failed invasive treatment.

EVALUATION - INTERNATIONAL PROSTATE SYMPTOM SCORE

It is known as 'American urological association symptom index' (AUASI). The Measurement Committee of the American urological association (AUA) developed the IPSS/AUASI.[20] AUA/IPSS symptom score is reliable, validated and most clinically useful scale to subjectively measure the symptoms and problem magnitude of the patients with benign enlargement of prostate. IPSS alone cannot be used to confirm the diagnosis of prostate enlargement. By the IPSS,we can grade the symptom severity, assessment of responsiveness to therapy and used to detect the symptom progression in patients with BPH who are managed with conservative management.

The IPSS score consists of seven questions corresponds to symptoms commonly seen in patients with BPH. They are,

1. Incomplete emptying,
2. Frequency,
3. Intermittency,
4. Urgency,
5. Weak stream and
6. Straining
7. Nocturia

Every question have zero to five points when all added together gives a score between zeros to thirty five. Point 0 stands for not at all patient experienced the symptom and 5 for almost always patient having the symptoms.

Based on total IPSS patients can be classified into having mild, moderate or severe symptoms. [22]

0-7 - Mild symptoms

8-19 - Moderate symptoms

20-35 - Severe symptoms

Only the assessment of IPSS alone will not be helpful in confirming the diagnosis of BPH, because patient's perception of symptoms will be different for each patients. Overall, the IPSS is reliable and valid through a variety of testing modalities. Apart from this score, varios types of scores like bother score and QoL index are useful in deciding the further management.

QUALITY OF LIFE (QOL) INDEX

The QoL index contain a single question item which can be used along with AUA symptom index(part of the IPSS score). QoL assess the severity to which the symptoms bothering the patient and the response ranges from 0-6.

UROFLOWMETRY

Uroflowmetry is "rate of urine flow over time." It is done by graphic measurement of the urinary flow rate during the act of micturition. It is commonly used because it is simple, non-invasive, and easily available.Peak flow rate can not differentiate the BOO from impaired detrusor contractility. It is used as screening test for voiding problems and to decide about the more complex urodynamic tests requirement.

Modern uroflowmeters use,

1. Use weight, (Gravimetric method)
2. Electrical capacitance, or
3. Rotating disc.

The commonly used meters are the Gravimetric flow meters which will function by readding the weight of the collected urine or by reading the hydrostatic pressure developing at the base of the collecting cylinder during the act of micturition. Flow rate measured in ml/second.

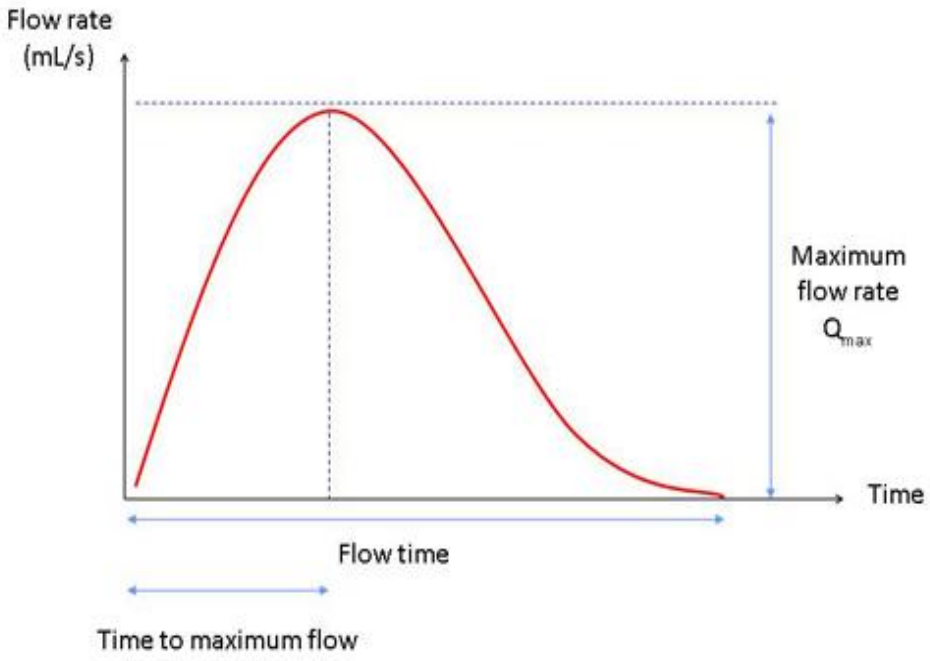


Figure 8- Normal bell shaped uroflow curve

The AHCPR Guideline for uroflowmetry,

1. Flow rate is not correct if patient passes less than 150 ml of urine.
2. Flow rate is the single best non-invasive test for detecting obstruction below the bladder. No "cut-off" value fixed so far.
3. The peak flow rate (PFR; Qmax) is more specific in BPH
4. No adjustment in values for change in age and decreasing voided volume.
5. When the Qmax > 15 mL/sec, it indicates poorer surgical outcomes after prostatectomy.
6. When A Qmax <15 mL/sec, it can not separate the bladder obstruction from decompensated bladder.

Qmax is useful to predict the response to surgery. It is also useful in the follow up of patients treated for BPH.

URETHROCYSTOSCOPY

Urethrocystoscopy is not routinely done for the BPH. It can be useful in the following conditions,

1. History of haematuria,
2. Suspected urethral stricture disease
3. Suspected neoplasm of bladder
4. Prior surgery
5. When surgical treatment is planned.

MANAGEMENT

Management of men with BPH depends on symptom severity which is assessed by IPSS and other associated factors and patient's willingness for given treatment.Like any other disease both medical and surgical managements are available apart from watchful waiting.

Watchful waiting will be useful for patients with mild or moderate IPSS score which is not affected the day today activities of the patient.

Treatment options are available for patients with bothersome moderate to severe symptoms of BPH (IPSS > 8) include watchful waiting and the medical, minimally invasive, or open surgical treatment.

In the medical management, alpha blockers or 5 alpha reductase inhibitors are commonly used.The various minimally invasive and endoscopic procedures like TURP, Transurethral needle ablation of prostate (TUNA), transurethral ultrasound–guided laser-induced prostatectomy (TULIP), transurethral vaporization of the prostate (TUVP), transurethral incision of prostate (TUIP) are various endoscopic options available for the treatment of BPH . Surgical treatment provides sustainable long term results when it is compare with the medical treatment in the management of BPH.

MEDICAL MANAGEMENT

For the medical treatment of enlarged prostate, two groups of drugs like alpha receptor blockers and 5-alpha reductase inhibitors are available. [51]

1)Alpha blockers

It act by decreasing the tone of the bladder neck and prostatic smooth muscle. They are divided into

1. Non selective - Phenoxybenzamine
2. Alpha 1 selective – Prazosin, Alfuzosin IR, Indormin.
3. Long acting alpha I selective - Doxazosin, Terazosin, Alfuzosin SR
4. Super selective - Tamsulosin and Silodosin.

Most commonly used alpha blocker is Tamsulosin which is super selective alpha blocker.Nowdays Silodocin is also used.

2)The 5 alpha reductase inhibitors

, It inhibits 5 alpha reductase enzyme which converts testosterone into dihydrotestosterone. The drugs commonly used are finasteride and dutasteride. They reduces the prostate size on long term treatment and. 20%

reduction in volume has been reported with finasteride use alone. Eventhough the safety and efficacy of these drugs are well established but the clinical improvement is modest and not sustainable. Patients with mild to moderate symptoms on drugs slowly progress into severe symptoms, may require surgical procedure as a definitive treatment.Pharmacotherapy will be useful in patients with mild symptoms and small size prostate glands.

SURGICAL MANAGEMENT

Endoscopic transurethral resection of the prostate(TURP) is the most commonly performed surgical procedure and this is considered as gold standard for the treatment of BPH. In the initial stages, complications of TURP occur more commonly. But nowdays with the available better optics, the complications rates are reduced.

HISTORY OF ELECTROSURGERY AND THE RESECTOSCOPE

The invention of incandescent lamp by Edison, the cystoscope by Nitze and Lieter, the introduction of fenestrated tube by Hugh Hampton-Young and the resection wire loop by McCarthy were very important steps in the endourology field.It reduced the rate of open surgeries in BPH and cause less morbidity to the patient with good results.

In 1932 McCarthy introduced tungsten loop for resection and it was developed with available cystoscope, light and electrical power and high resistance loop. In 1970 introduction of Hopkins rod lens system and fiberoptic lighting made visualization better. In 1980 video urological procedures were introduced. Thick loop electrode will be useful for increased coagulation while removing larger prostatic tissue bits.

TURP

Usually, TURP is done under spinal anaesthesia. First cystourethroscopy done after dilating the external urethral meatus and the fossa navicularis.A thorough inspection of urethra, verumontanum, prostate, bladder neck, entire bladder mucosa and both ureteric orifices are done.For the resection of the prostate, 24 Fr or 27 Fr resectoscope is used.We use 24 Fr resectoscope sheath routinely. Either sterile water or glycine is used as the irrigant. The technique used for resection was first described and standardised by Nesbit in 1943and later modified by many investigators. But the basic principles remain the same. They are,

a) Controlled resection,
b) Limiting the resection proximal to verumontanum,
c) Not violating the capsule and
d) Not undermining the bladder neck

Complications of TURP include,

1. Bleeding,
2. Trans urethral resection syndrome,
3. Post -operative incontinence,
4. Failure to void.

Role of 5Alpha reductase inhibitors in TURP Complication;

Since the embryonic development of the prostate is dependent on the dihydrotestosterone,there is a role for the 5alpha reductase inhibitors in reducing the TURP complication. Finasteride is a type 2 5α-reductase inhibitor, and the Dutasteride is a dual inhibitor of both type 1 and type 2 5α-reductase which are the important drugs commonly used for androgen suppression in BPH.[(44)]

Gross hematuria is rare manifestation of BPH.Many randomized, double-blind, placebo-controlled study demonstrated that Finasteride prevents recurrent gross hematuria secondary to BPH[10]. Gross refractory hematuria recurred within 1 year for 63% and 14% of men randomized to placebo and Finasteride, respectively. Dutasteride is a dual inhibitor of 5α-reductase types 1 and 2 and it has a greater impact on suppressing serum DHT levels[17].Since the Finasteride was proven drug to reduce the TURP complication,we can expect the same role from Dutasteride also.

Impotence and decreased ejaculatory volume are the adverse effects from the 5ARIs.Many literature also suggests finasteride and dutasteride may be offered to men with hematuria secondary to friable prostatic tissue and in those men with LUTS due to enlarged prostate.They alter the natural history of urinary retention in men with enlarged prostates.

Antiandrogens have also been investigated for BPH. Many studies failed to demonstrate statistically significant treatment-related efficacy for antiandrogen. The equivocal efficacy and problematic toxicity of antiandrogens limited the enthusiasm for marketing these drugs for the treatment of BPH.Some studies demonsrated that Dutasteride also reduce the microvessel density of prostatic tissue in TURP specimens and reduce the bleeding complication in TURP.R. But Shanmugasundaram et al showed that Dutasteride did not reduce the bleeding complication significantly when compared to placebo.

MATERIALS & METHODS

The following are the materials and methods employed for the present study titled :**The Role Of Dutasteride In Reducing The Complications Of Transurethral Resection Of Prostate**

Period of study:

The study is done between March 2013 and Feb 2014

Type:

This is a prospective randomised control trail study

Place:

The study is conducted in the Department of Urology, Rajiv Gandhi Government General Hospital & Madras Medical College, Chennai.

Inclusion criteria

Men with Benign prostate enlargement and prostate volume more than 30cc with acute urinary retention who are undergoing TURP.

Exclusion criteria

- H/O prostatic surgery in the past.
- Prostatic disease other than BPH
- Who had 5Alpha reductase in the past 12 months

- Requirement of Aspirin,NSAIDS during the restricted periods,
- Bleeding disorder,
- Liver diseases

Method of Study

Institutional Ethics Committee approval was obtained(EC.NO-31032013). Informed consent was taken from all patients who underwent surgery. All patient details were recorded as per the proforma(Appendix A). Patients were randomized into three groups of 50 each to undergo TURP.

Group 1-receiving placebo for two weeks preoperatively and two weeks postoperatively.

Group 2-receiving Tab.Dutasteride 0.5mg BD, for 2weeks preoperatively and two weeks postoperatively

Group 3-receiving Tab.Finasteride 5mg BD,two weeks preoperatively and 2 weeks postoperatively.

Monopolar TURP was done with single stem TUR loop and Glycine as a irrigant. The settings employed was 110W cutting and 80W coagulation for the resection.

The setup of instruments for TURP resection, includes 24 – Fr. Karl Storz non-continuous flow sheath with blind and visual obturator, resectoscope, monopolar loop, high frequency cord, 30 degree Karl Storz telescope and unipolar diathermy.

PREOPERATIVE WORKUP

Complete clinical history was taken and through clinical examination was done for all the patients.Complete urine analysis, Urine culture and sensitivity were done and patients with positive cultures were treated with appropriate antibiotics. Complete haemogram and renal function tests with electrolytes, coagulation parameters, Blood grouping and typing were done in preoperative period.

FIGURE 9 USG BLADDER WITH PROSTATE ENLARGEMENT

X-ray KUBU and Ultra sonogram of KUB region was done for all the patients.The patients were randomly divided into 3groups,which each group consists of 50 patients.Those patients with H/O prostatic surgery in the past &prostatic disease other than BPH(25 in No)**,w**ho had 5Alpha reductase in the

past 12 months(29 in No),requirement of Aspirin,NSAIDS during the restricted periods(12 in NO),bleeding disorder(2 in No),liver diseases(7 in No) were excluded(Total 55 in No). .

For the Group 1 patients started placebo ,group 2 patients started Tab.Dutasteride 0.5mg BD,group3 patients started Tab.Finasteride 5mg BD two weeks preoperatively and the same treatment was continued postoperatively for 2weeks.The primary efficacy outcome is total blood loss during transurethral resection of prostate which was done under spinal anaesthesia.Secondary efficacy outcomes are the incidence of clot retention,requirement of blood transfusion,failure to void after the cathter removal and the incidence of urinary tract infection.All the patients were monitored for 2weeks in the preoperative period and 4 weeks in the postoperative period.

INTRAOPERATIVE WORK UP

Trans Urethral Resection of Prostate was done by the experionsed urologists. The resection time of TURP was calculated from the period of initiation of resection to the removal of resectoscope sheath.The 3 way Foley catheter was inserted at the end of the procedure and irrigation was started and continued postoperatively. For all patients, any intraoperative complications and the resected prostatic tissue weight in gm were noted. The resected prostatic chips from the prostatic hyperplasia and the prostatic urethra were

send separatively for microvessel density(MVD) estimation and the histopathological examination.

POSTOPERATIVE WORK UP

Postoperative haemoglobin and packed cell volume(PCV) were done on the first postoperative day after the continuous irrigation was stopped.Preoperative Hb/PCV were compared with the postoperative Hb/PCV for the blood loss in all the three groups.Prostatic chips from the prostatic hyperplasia and the prostatic urothelium were fixed in 10% formalin and stored at 4 degree Celsius and incubated with CD34 monoclonal immunohistochemical antibody before staining wth haematoxylin& eosin.The most microvessels within an area of 0.754mm^2 was counted by light microscopy with 200 times magnification .

Postoperatively all patients were monitored for haematuria,clot retention,blood transfusion requirement,altered sensorium,urinary tract infection and any change in vital parameters.Bladder Irrigation continued till the next morning as a protocol for all patients and the foley Catheter was removed on fourth postoperative day and discharged on the same day.They are compared with postoperative complications like clot retention,blood transfusion requirement,failure to void after the catheter removal and the urinary tract infection.Patients were reviewed with biopsy report after a week and all the three group patients were followed up for 4 weeks in postoperative period for the TURP complication and the drug side effects.

STATISTICAL ANALYSIS

Descriptive statistics were used to illustrate the study population. The statistical significance of these correlations was assessed using a two sided p-value. A p-value of <0.05 was considered as statistically significant. The Chi Square test and ANOVA test were used to assess the statistical significance. Multiple comparision test and paired T test are also used for the comparision of various descriptive within the groups. A commercially available computer software package (Statistical Package for the Social Sciences (SPSS) version 17) was used for statistical analysis.

RESULTS

Total of 150 patients were completed the study and the 3 randomized groups were compared.

Group 1 received the placebo 2weeks preoperatively and 2 weeks postoperatively ,

Group 2 received the Tab.Dutasteride 0.5mg BD 2 weeks preoperatively and 2 weeks postoperatively,

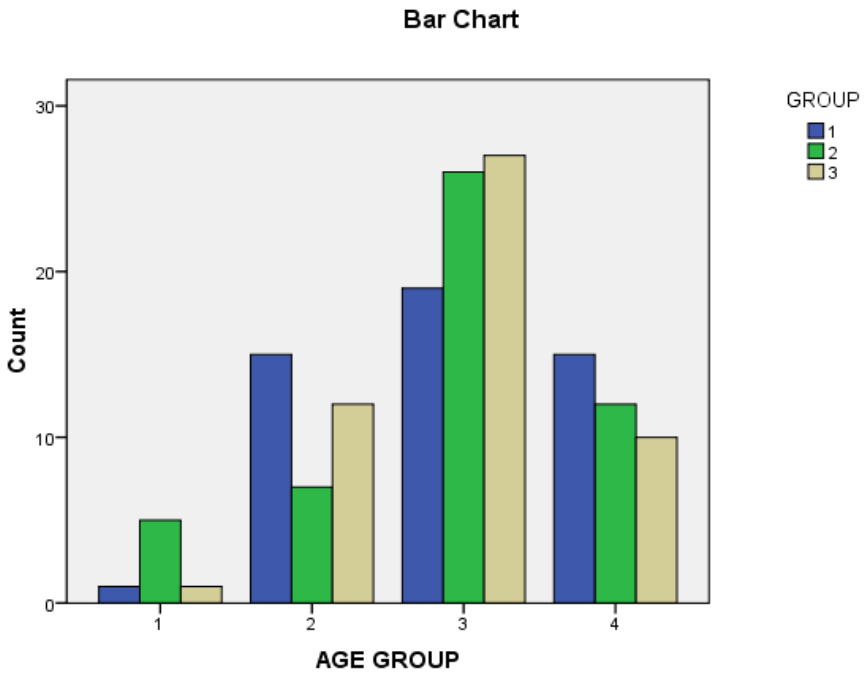
Group 3 received the Tab.Finasteride 5 mg BD 2 weeks preoperatively and 2 weeks postoperatively,

Demographic data of the group 1,group 2 and group 3 are given in Table 1.

AGE GROUP

	YEARS		**GROUP**			
			1	**2**	**3**	**Total**
AGE GROUP	1(40-50)	Count	1	5	1	7
		% within GROUP	2.0%	10.0%	2.0%	4.7%
		% of Total	.7%	3.3%	.7%	4.7%
	2(>50-60)	Count	15	7	12	34
		% within GROUP	30.0%	14.0%	24.0%	22.7%
		% of Total	10.0%	4.7%	8.0%	22.7%
	3(>60-70)	Count	19	26	27	72
		% within GROUP	38.0%	52.0%	54.0%	48.0%
		% of Total	12.7%	17.3%	18.0%	48.0%
	4(>70-80)	Count	15	12	10	37
		% within GROUP	30.0%	24.0%	20.0%	24.7%
		% of Total	10.0%	8.0%	6.7%	24.7%
	Total	Count	50	50	50	150
		% within GROUP	100.0%	100.0%	100.0%	100.0%
		% of Total	33.3%	33.3%	33.3%	100.0%

Chi square= 10.064 p= 0.122 not significant.



Age group 1;40-50yrs, Group 2;>50-60 yrs,Group 3;>60-70yrs,Group 4>70 yrs

ANOVA

AGE

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	6.173	2	3.087	.047	.954
Within Groups	9727.000	147	66.170		
Total	9733.173	149			

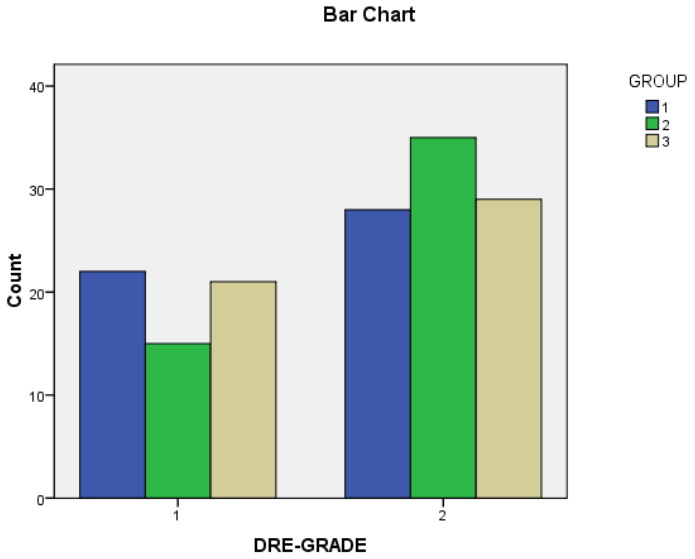
As for as age is considered, it is not significant in between the 3 groups.

Mean age of patients in group 1,2,3 was 65.70,65.26,65.68 years respectively.72% in group 1,48% in group 2 and group 3 were in the 60-70 years which is the common age group for benign prostate enlargement.The maximum age in group 1,2,3 was 85,81 and 85 years respectively.As for as age was considered, all the three groups were equally matched.

DRE-GRADE GROUPS

			GROUP			
			1	**2**	**3**	**Total**
DRE-GRADE	1	Count	22	15	21	58
		% within GROUP	44.0%	30.0%	42.0%	38.7%
		% of Total	14.7%	10.0%	14.0%	38.7%
	2	Count	28	35	29	92
		% within GROUP	56.0%	70.0%	58.0%	61.3%
		% of Total	18.7%	23.3%	19.3%	61.3%
	Total	Count	50	50	50	150
		% within GROUP	100.0%	100.0%	100.0%	100.0%
		% of Total	33.3%	33.3%	33.3%	100.0%

Chi square= 2.418 p= 0.299 Not significant.



In digital rectal examination, 61.3% patients had grade 2 and 38.7% had grade 1 benign prostate enlargement.All the 3 groups had approximately equal distribution of grade 1&2 benign prostate enlargement without significant p value. Within the groups,smallest prostate volume is 30.09ml and the largest prostate volume is 65.42ml. When the prostate volume is compared in between the 3 groups,the mean difference was not significant.

Descriptives

PROSTATE VOLUME(ml)

					95% Confidence Interval for Mean	
	N	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound
1	50	40.143600	4.7211317	.6676689	38.801869	41.485331
2	50	43.418400	8.8101061	1.2459371	40.914596	45.922204
3	100	42.665800	9.0532749	.9053275	40.869434	44.462166
Total	200	42.223400	8.1804135	.5784426	41.082736	43.364064

PROSTATE VOLUME

ANOVA

PROSTATE VOLUME(ml)

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	307.251	2	153.626	2.326	.100
Within Groups	13009.662	197	66.039		
Total	13316.914	199			

Multiple Comparisons

PROSTATE VOLUME(ml)

(I) GROUP	(J) GROUP				95% Confidence Interval	
		Mean Difference (I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
1	2	-3.2748000*	1.6252864	.045	-6.479993	-.069607
	3	-2.5222000	1.4075393	.075	-5.297979	.253579
2	1	3.2748000*	1.6252864	.045	.069607	6.479993
	3	.7526000	1.4075393	.593	-2.023179	3.528379
3	1	2.5222000	1.4075393	.075	-.253579	5.297979
	2	-.7526000	1.4075393	.593	-3.528379	2.023179
*. The mean difference is significant at the 0.05 level.						

. The mean prostate volume in group1,2 and 3 were 40.14ml,43.41ml,42.66ml respectively. Within the groups,smallest prostate volume is 30.09ml and the largest prostate volume is 65.42ml. When the prostate volume was compared in between the all 3 groups,the mean difference was not significant.

Preoperative Haemoglobin

ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1.013	2	.506	3.955	.021
Within Groups	18.822	147	.128		
Total	19.835	149			

PREOPERATIVE HB

GROUP(I)	GROUP (J)				95% Confidence Interval	
		Mean Difference (I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
1 MEAN 10.41	2	-.168*	.072	.020	-.31	-.03
	3	-.180*	.072	.013	-.32	-.04
2 MEAN 10.58	1	.168*	.072	.020	.03	.31
	3	-.012	.072	.867	-.15	.13
3 MEAN 10.59	1	.180*	.072	.013	.04	.32
	2	.012	.072	.867	-.13	.15

The mean difference is significant at the 0.05 level

Preoperative Haemoglobin.

The mean preoperative haemoglobin was comparable in between the 3 groups(10.41-10.59).When the multiple comparisions were made in between the 3 groups,there is no significant mean difference in the preoperative haemoglobin level.

Preoperative PCV

GROUP(I)	GROUP (J)				95% Confidence Interval	
		Mean Difference (I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
1 MEAN 31.08	2	-.280	.223	.211	-.72	.16
	3	-.280	.223	.211	-.72	.16
2 MEAN 31.36	1	.280	.223	.211	-.16	.72
	3	.000	.223	1.000	-.44	.44
3 MEAN 31.36	1	.280	.223	.211	-.16	.72
	2	.000	.223	1.000	-.44	.44

PREOPERATIVE PCV

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	2.613	2	1.307	1.051	.352
Within Groups	182.720	147	1.243		
Total	185.333	149			

The mean preoperative packed cell volume was comparable in between the 3 groups(31.08-31.36).When the multiple comparisions were made in between the 3 groups,there was no significant mean difference in the preoperative packed cell volume level.

TURP RESECTION TIME(mt) Multiple Comparisons

GROUP(I)	GROUP (J)				95% Confidence Interval	
		Mean Difference (I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
1 MEAN 54.84	2	-2.220*	1.038	.034	-4.27	-.17
	3	.220	1.038	.832	-1.83	2.27
2 MEAN 57.06	1	2.220*	1.038	.034	.17	4.27
	3	2.440*	1.038	.020	.39	4.49
3 MEAN 54.62	1	-.220	1.038	.832	-2.27	1.83
	2	-2.440*	1.038	.020	-4.49	-.39

*. The mean difference is significant at the 0.05 level.

ANOVA

RESECTION TIME(mt)

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	182.173	2	91.087	3.382	.037
Within Groups	3959.320	147	26.934		
Total	4141.493	149			

TURP RESECTION TIME

The mean TURP resection time was comparable in between the 3 groups(54.62-57.06).The maximum TURP resection time in group1,2,3 was 68 mt,65mt and 65mt respectively.The minimum TURP resection time was 45mt,46mt and45mt respectively. When the multiple comparisions were made in between the 3 groups,there was no significant mean difference in the transurethral resection time of prostate.

Multiple Comparisons

TURP TISSUE WEIGHT (gm)

(I) GROUP	(J) GROUP				95% Confidence Interval	
		Mean Difference (I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
1 MEAN 24.8	2	-5.800*	1.182	.000	-8.14	-3.46
	3	-5.640*	1.182	.000	-7.98	-3.30
2 MEAN 30.6	1	5.800*	1.182	.000	3.46	8.14
	3	.160	1.182	.893	-2.18	2.50
3 MEAN 30.44	1	5.640*	1.182	.000	3.30	7.98
	2	-.160	1.182	.893	-2.50	2.18

*. The mean difference is significant at the 0.05 level.

ANOVA

RESECTED PROSTATIC TISSUE WEIGHT(gm)

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1091.253	2	545.627	15.610	.000
Within Groups	5138.320	147	34.955		
Total	6229.573	149			

The mean transurethral resected prostatic weight in group 1 is 24.8gm,group 2 is 30.6gm and the group 3 is 30.4 gm.The maximum resected prostatic tissue weight was 42 gm in group 3.In the multiple comparisions,significant mean difference was present when the placebo group is compared with the Dutasteride and the Finasteride group.It indicates that large amount of prostatic tissue can be resected when the 5ARI is started preoperatively.

Multiple Comparisons

MVD-SUBURETHRAL PROSTATIC TISSUE

(I) GROUP	(J) GROUP				95% Confidence Interval	
		Mean Difference (I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
1 MEAN 23.315	2	7.7548000*	.4873811	.000	6.791621	8.717979
	3	9.2662000*	.4873811	.000	8.303021	10.229379
2 MEAN 15.561	1	-7.7548000*	.4873811	.000	-8.717979	-6.791621
	3	1.5114000*	.4873811	.002	.548221	2.474579
3 MEAN 14.049	1	-9.2662000*	.4873811	.000	-10.229379	-8.303021
	2	-1.5114000*	.4873811	.002	-2.474579	-.548221

ANOVA

MVD-SUBURETHRAL PROSTATIC TISSUE

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	2471.395	2	1235.698	208.082	.000
Within Groups	872.961	147	5.939		
Total	3344.356	149			

Micro Vessel Density(MVD) –Suburethral Prostatic Tissue

The mean micro vessel density of suburethral prostatic tissue from Group 1, Group 2 and Group 3 were 23.3158,15.561 and 14.0496 respectively.When multiple comparisions were made between the placebo group and 5ARI groups significant mean difference was present.It indicated that MVD was significantly reduced in the suburethral prostatic epithelium by preoperative Dutasteride and Finasteride group when compared with the placebo group.

Multiple Comparisons

MVD-HYPERPLASTIC PROSTATICTISSUE

(I) GROUP	(J) GROUP				95% Confidence Interval	
		Mean Difference (I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
1 MEAN 16.089	2	1.4426000*	.1848879	.000	1.077218	1.807982
	3	3.3606000*	.1848879	.000	2.995218	3.725982
2 MEAN 14.646	1	-1.4426000*	.1848879	.000	-1.807982	-1.077218
	3	1.9180000*	.1848879	.000	1.552618	2.283382
3 MEAN 12.728	1	-3.3606000*	.1848879	.000	-3.725982	-2.995218
	2	-1.9180000*	.1848879	.000	-2.283382	-1.552618

*. The mean difference is significant at the 0.05 level.

ANOVA

MVD-HYPERPLASTIC PORTION

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	284.224	2	142.112	166.293	.000
Within Groups	125.624	147	.855		
Total	409.849	149			

The mean micro vessel density of hyperplastic prostatic tissue from Group 1, Group 2 and Group 3 were 16.089,14.646 and 12.728 respectively.When multiple comparisions were made between the placebo group and Dutasteride ,Finasteride groups, significant mean difference was present.

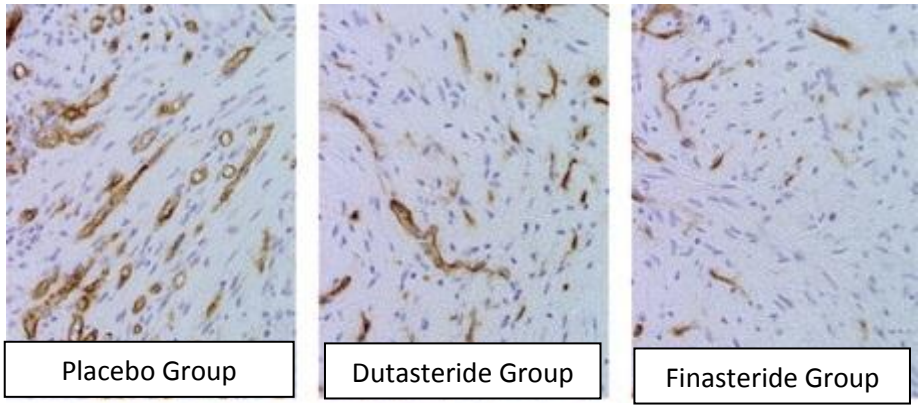


FIG 10 Micro vessel density CD 34 IHC- TURP PROSTATIC TISSUE

POST OPERATIVE HB - Multiple Comparisons

(I) GROUP	(J) GROUP				95% Confidence Interval	
		Mean Difference (I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
1 MEAN 9.45	2	-.1660000	.0994814	.097	-.362598	.030598
	3	-.1720000	.0994814	.086	-.368598	.024598
2 MEAN 9.61	1	.1660000	.0994814	.097	-.030598	.362598
	3	-.0060000	.0994814	.952	-.202598	.190598
3 MEAN 9.62	1	.1720000	.0994814	.086	-.024598	.368598
	2	.0060000	.0994814	.952	-.190598	.202598

ANOVA

POST OPERATIVE HB

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.953	2	.476	1.926	.149
Within Groups	36.370	147	.247		
Total	37.323	149			

The mean postoperative haemoglobin from Group 1,Group 2 and Group 3 is 9.452, 9.618 and 9.624 respectively. When multiple comparisions were made between the placebo group and Dutasteride ,Finasteride groups, there was no significant mean difference in the post operative haemoglobin.

POST OPERATIVE PCV Multiple Comparisons

(I) GROUP	(J) GROUP				95% Confidence Interval	
		Mean Difference (I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
1	2	-.520	.278	.063	-1.07	.03
	3	-.440	.278	.115	-.99	.11
2	1	.520	.278	.063	-.03	1.07
	3	.080	.278	.774	-.47	.63
3	1	.440	.278	.115	-.11	.99
	2	-.080	.278	.774	-.63	.47

POST OPERATIVE PCV-ANOVA

-

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	7.840	2	3.920	2.032	.135
Within Groups	283.600	147	1.929		
Total	291.440	149			

The mean postoperative packed cell volume from Group 1,Group 2 and Group 3 is 28.16, 28.68, 28.60 respectively. When multiple comparisions were made between the placebo group and Dutasteride ,Finasteride groups, there was no significant mean difference in the post operative packed cell volume.

T-Test Table: Paired Samples Statistics-Hb loss in TURP

Group 1(Placebo)

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PREOP HB	10.41	50	.394	.056
	POSTOP HB	9.452	50	.5697260	.0805714
Pair 2	PREOP PCV	31.08	50	1.158	.164
	POSTOP PCV	28.16	50	1.490	.211

Paired Samples Test (Hb loss in GROUP 1-PLACEBO)

Paired Differences-95% Confidence Interval of the Difference

		Lower	Upper	t	df	Sig. (2-tailed)
Pair 1	HB - POST OP HB	.7866316	1.1373684	11.024	49	.000
Pair 2	PCV - POST OP PCV	2.451	3.389	12.501	49	.000

When the preoperative and postoperative Hb/PCV were compared in placebo group ,significant difference was present in the blood loss.

Paired Samples Test(Blood loss in GROUP 2-Dutasteride)

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PREOP- HB	10.60	50	.495	.070
	POST OP -HB	9.618000	50	.4543172	.0642501
Pair 2	PREOP-PCV	31.36	50	1.156	.164
	POST OP- PCV	28.68	50	1.406	.199

Paired Samples Test(Blood loss in GROUP 2-Dutasteride)

		Lower	Upper	t	df	Sig. (2-tailed)
Pair 1	PREOP-HB POST OP HB	.8136523	1.1503477	11.722	49	.000
Pair 2	PREOP PCV POST OP PCV	2.252	3.108	12.598	49	.000

When the preoperative and postoperative Hb/PCV were compared in the Dutasteride group, significant difference was present in the blood loss.

Paired Samples Test(Blood loss in GROUP 3 - Finasteride)

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	HB	10.66	50	.479	.068
	POST OP HB	9.624000	50	.4596183	.0649998
Pair 2	PCV	31.36	50	1.025	.145
	POST OP PCV	28.60	50	1.262	.178

Paired Samples T Test- Group 3(Finasteride)

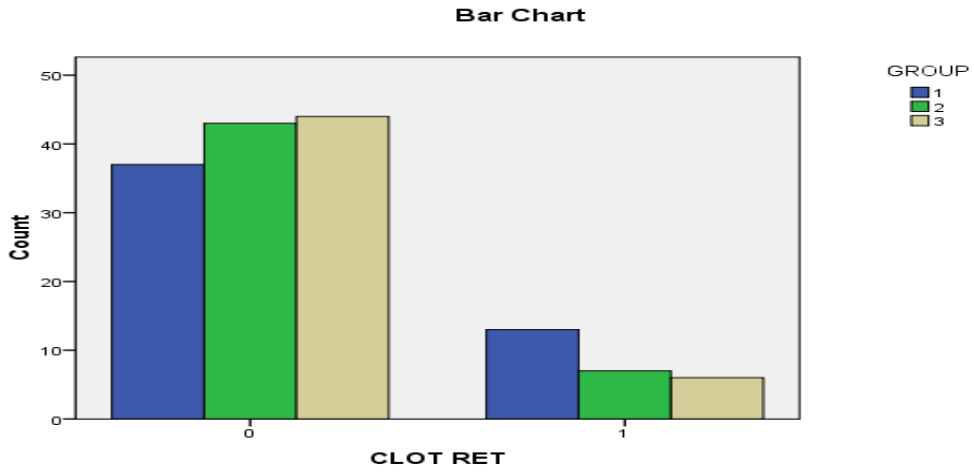
		Paired Differences				
		95% Confidence Interval of the Difference				
		Lower	Upper	t	df	Sig. (2-tailed)
Pair 1	HB - POST OP HB	.8537302	1.2182698	11.422	49	.000
Pair 2	PCV - POST OP PCV	2.408	3.112	15.762	49	.000

When the preoperative Hb/PCV and postoperative Hb/PCV were compared in the Finasteride group, significant difference was present in the blood loss.

CLOT RETENTION- GROUP Crosstab

			GROUP			
			1	2	3	Total
CLOT RET	0	Count	37	43	44	124
		% within GROUP	74.0%	86.0%	88.0%	82.7%
		% of Total	24.7%	28.7%	29.3%	82.7%
	1	Count	13	7	6	26
		% within GROUP	26.0%	14.0%	12.0%	17.3%
		% of Total	8.7%	4.7%	4.0%	17.3%
	Total	Count	50	50	50	150
		% within GROUP	100.0%	100.0%	100.0%	100.0%
		% of Total	33.3%	33.3%	33.3%	100.0%

Chi square= 4.001 P= 0.135,not significant



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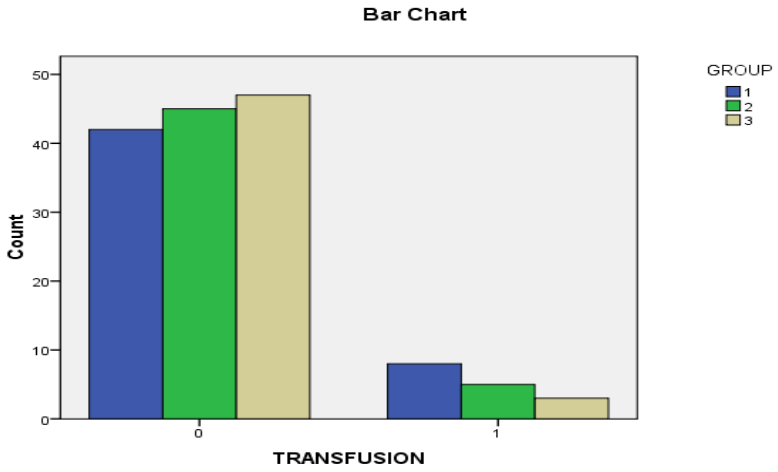
Postoperative clot retention is occur 26%,14%,12% in Group1,2,3 respectively without significant p value.

TRANSFUSION * GROUP Crosstab

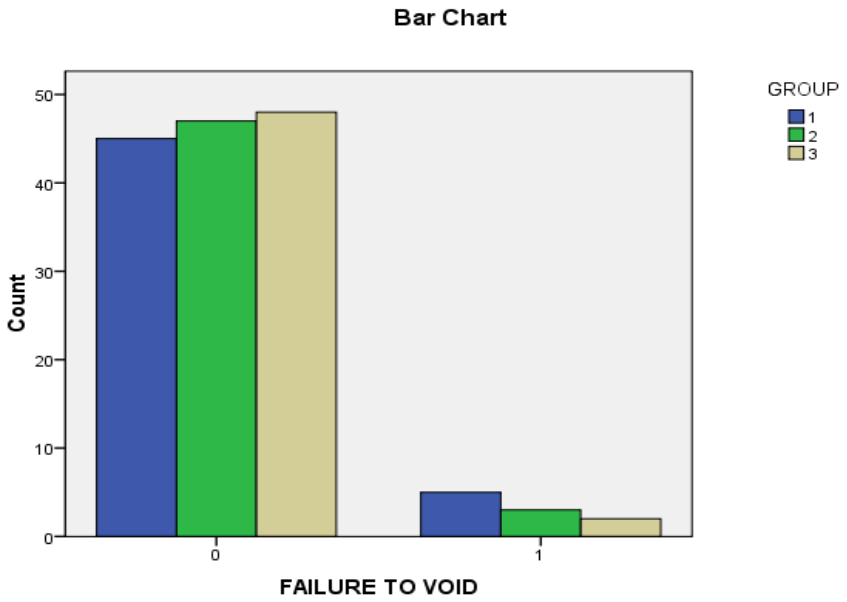
			GROUP			
			1	**2**	**3**	**Total**
TRANSFUSION	0	Count	42	45	47	134
		% within GROUP	84.0%	90.0%	94.0%	89.3%
		% of Total	28.0%	30.0%	31.3%	89.3%
	1	Count	8	5	3	16
		% within GROUP	16.0%	10.0%	6.0%	10.7%
		% of Total	5.3%	3.3%	2.0%	10.7%
	Total	Count	50	50	50	150
		% within GROUP	100.0%	100.0%	100.0%	100.0%
		% of Total	33.3%	33.3%	33.3%	100.0%



Chi square= 2.659 P= 0.265 Not significant. Postoperative blood transfusion was given 16%,10%,6% in Group 1,2,3 respectively without significant p value.

FAILURE TO VOID * GROUP- Crosstab

			GROUP			
			1	**2**	**3**	**Total**
FAILURE TO VOID	0	Count	45	47	48	140
		% within GROUP	90.0%	94.0%	96.0%	93.3%
		% of Total	30.0%	31.3%	32.0%	93.3%
	1	Count	5	3	2	10
		% within GROUP	10.0%	6.0%	4.0%	6.7%
		% of Total	3.3%	2.0%	1.3%	6.7%
	Total	Count	50	50	50	150
		% within GROUP	100.0%	100.0%	100.0%	100.0%
		% of Total	33.3%	33.3%	33.3%	100.0%



Chi square= 1.500 p= 0.472 Not significant. Postoperative failure to void was occur 10%,6%,4% in Group 1,2,3 respectively without significant p value.

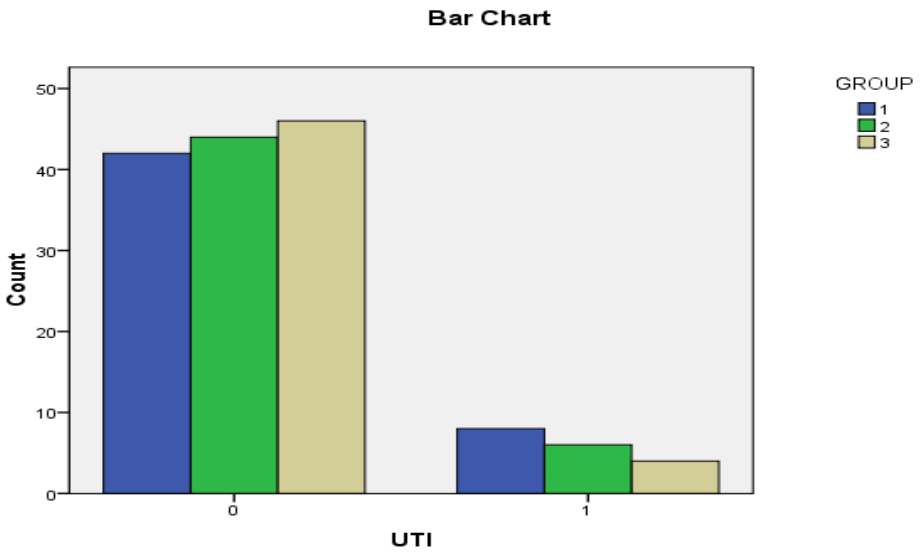
UTI * GROUP Crosstab

			GROUP			
			1	**2**	**3**	**Total**
UTI	0	Count	42	44	46	132
		% within GROUP	84.0%	88.0%	92.0%	88.0%
		% of Total	28.0%	29.3%	30.7%	88.0%
	1	Count	8	6	4	18
		% within GROUP	16.0%	12.0%	8.0%	12.0%
		% of Total	5.3%	4.0%	2.7%	12.0%
.	Total	Count	50	50	50	150
		% within GROUP	100.0%	100.0%	100.0%	100.0%
		% of Total	33.3%	33.3%	33.3%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.515[a]	2	.469
Likelihood Ratio	1.541	2	.463
Linear-by-Linear Association	1.505	1	.220
N of Valid Cases	150		

Postoperative Urinary Retention was occur in 16%,12% and 8% in group 1,2 and 3 respectively, without statistically significant difference .



Postoperative urinary tract infection was occur 16%,12%,8% in Group 1,2,3 respectively without significant difference.

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DISCUSSION

The primary objective of this randomised controlled study was to assess whether preoperative treatment with Dutasteride reduces the bleeding complication in TURP for BPH.

Many studies demonstrated that Finasteride has definite role in reducing the bleeding complication of TURP [23]. In analysing the results of three groups, all the group had similar demographic data.About 48% patients are in the 60-70 age group with the mean age of 65.55. Robert G. Hahn, Tim Fagerström*, Teuvo L.J. Tammela et al [18] had similar study with the mean age of 67yrs. In the digital rectal examination 61% had Grade 2 benign prostate enlargement and any significant mean difference was not present within the groups.

The mean prostate volume was 42.23ml.J. A.Arratia-Maqueo et al had similar study which had mean prostate volume 66.8cm^3 in Dutasteride group and 57cm^3 in control group[17]. The mean preoperative haemoglobin was 10.53gm/dl and the mean packed cell volume is 31.27%. The prostate volume,preoperative haemoglobin and the packed cell volume didn't have any significant mean difference.

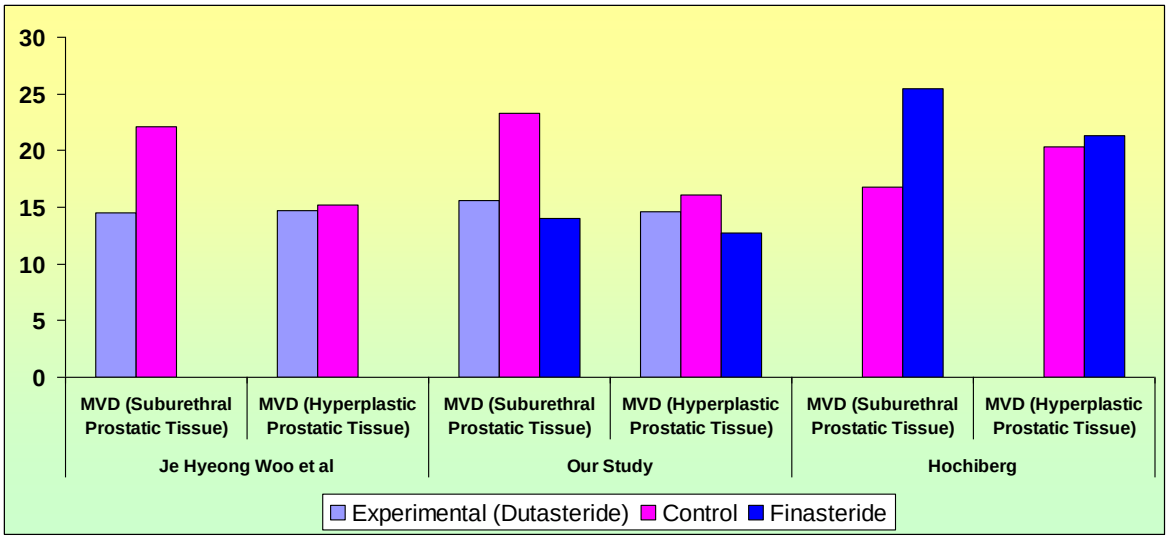
Robert G. Hahn, Tim Fagerström*, Teuvo L.J. Tammela et al**,** showed that the mean TURP operating time was 45 mts and the mean weight of

resected prostatic tissue was 25gm[18] .This study also showed almost similar results with the mean transurethral prostatic resection time is 55.51sec within the groups and the mean transurethral resected prostatic weight was 28.61gm. The mean TURP tissue weight from the placebo, Dutasteride and Finasteride group was 24.8gm,30.6gm,30.4gm respectively.When the placebo group was compared with other groups regarding TURP tissue weight.significant mean difference was present.Compared to the Dutasteride,Finasteride group,in placebo group the mean resected prostatic tissue weight was less(30.6gm,30.4gm Vs 24.8 gm).It indicates that by giving preoperative 5alpha reductase inhibitors,the resection of prostatic tissue weight in TURP can be increased.

The microvessel density(MVD) of suburethral portion of prostatic tissue was higher in placebo group(23.31) than in Dutasteride(15.56) and Finasteride group(14.04).David A A Hochberg et al showed MVD in Finasteride and placebo group was 20.2+5.3 Vs14.0+2.8 which was similar to this study.Je Hyeong Woo Korean et al showed that the mean MVD in the suburethral portion of prostatic tissue in Dutasteride and Placebo was 22.19 Vs 14.47,p value 0.026.

The microvessel density(MVD) of hyperplastic portion of prostatic tissue in placebo group(16.08) was slightly higher than Dutasteride(14.64) and Finasteride group(12.72) in this study. Je Hyeong Woo Korean et al showed

that the mean MVD in the hyperplastic portion of prostatic tissue in Dutasteride and Placebo was 14.72 Vs 15.24,p value 0.801. David A A Hochberg et al showed MVD in hyperplasti portion in Finasteride and placebo group was 17.5+2.8 Vs 16.7+4.6.Je Hyeong Woo et al showed that the mean MVD in suburethral portion of prostatic tissue in Dutasteride treated patients was significantly lower than untreated patients(14.47 Vs 22.19 vessels per hpf,p=0.026).Some research suggests that the androgen controlled vascular endothelial growth factor is suppressed by 5alpha reductase inhibitors which was leading to decreased angiogenesis and the reduction of microvessel density.



Eventhough significant blood loss was present in all 3 groups due to TURP, when the preoperative and postoperative Hb/PCV were compared in between the groups and there was no statistically significant difference. The most practical way to quantify blood loss during TURP is by measuring Hb in

the irrigating fluid.Although Hb levels are only 5–10% of that found in whole blood, precision is ensured by using a highly sensitive photometer. In this study blood loss was calculated by comparing the preoperative and postoperative haemoglobin/PCV.

Postoperative clot retention from the group 1,2 and 3 was 26%,14%,12% respectively. Postoperative blood transfusion was required in 16%,10%,6% in groups respectively. R.Shanmugasundaram, Nitin S.Kekre et all showed clot retention occurred in 6-11% and 1-3% requirement of blood transfusion which was less than our study.

Failure to void was occurred 10%,6%,4% in group 1,2 and group 3 respectively.Postoperative urinary tract infection was occurred in 16%,12% and 8% in placepo,dutasteride and finasteride group respectively. The above mentioned complications were occurred in higher number in placebo group but there was no statistically significant differences among groups. R.Shanmugasundaram, Nitin S.Kekre et al showed AUR in 11-17% and UTI in 20-30% statistically without significant difference [(52)].

5 Alpha reductase inhibitor like Finasteride have been commonly used in the perioperative period to reduce the bleeding complication in TURP.It shrink the prostate size by inhibiting the VEGF and decreasing the microvessel density.Sandfeldt et al showed that Finasteride didn’t produce any difference

in blood loss in TURP.Like our study,David A, A Hochberg et al showed that Finasteride decreases suburethral prostatic microvessel density in BPH.

R.Shanmugasundaram, Nitin S.Kekre et al showed that preoperative Dutasteride did not reduce significantly bleeding complication in TURP eventhough it reduced the intraprostatic concentration of DHT[52].Pastore AL,Mariani et al showed six weeks preoperative Dutasteride treatment reduced the surgical bleeding in TURP.J.A.Arratia-Maqueo et al showed that no statistically significant difference were seen in bleeding complication in TURP by preoperative Dutasteride.Je Hyeong Woo et al showed that preoperative 2 weeks short term Dutasteride decreases suburethral prostatic microvessel density in BPH and reduce the bleeding complication in TURP.

This randomised study showed that 2weeks preoperative and 2 weeks postoperative Dutasteride 0.5mg BD significantly reduced the microvessel density in suburethral portion prostatic tissue in BPH patients and reduce the TURP bleeding complications like clot retention, blood transfusion requirement almost similar by the Finasteride.

CONCLUSION

1. The present study shows two weeks preoperative Dutasteride 0.5 mg BD treatment in BPH will reduce the microvessel density in suburethral portion of prostatic urothelium.
2. Preoperative Dutasteride will helpful for the larger amount of prostatic tissue resection in lesser time.
3. Eventhough the preoperative Haemoglobin and PCV were not significantly different from postoperative Hb/PCV,Dutasteride cause clot retention and blood transfusion in lesser number of post TURP patients.
4. When the Dutasteride is compared with Finasteride in reducing the TURP complication,it has efficacy almost similar to the Finasteride.

Preoperative Dutastride will reduce the TURP complication in BPH as Finasteride but needs further large randomized trials to confirm the efficacy with better statistically significant difference.

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PROFORMA

ROLE OF DUTASTERIDE IN REDUCING THE COMPLICATION OF TRANSURETHRAL RESECTION OF PROSTATE

SL No: Date:

Patient Name: Age/ Sex:

IP No:

Address:

Chief Complaint:

Presenting Illness:

Past Medical / Surgical History:

Personal History:

Family History:

General Examination:

Pulse: BP:

P/A: E/G:

DRE:

INVESTIGATIONS

HB

TC

DC

ESR

RBS

Blood Urea

Serum Creatinine

Serum Electrolytes

Blood Grouping & Typing

USG KUB

Urine R/E:

Urine C & S:

Prostate Volume:

X-Ray KUB

Others

S NO	Name	AGE	DRE-GRADE	USG PROSTATE(cm)	PROSTATE VOLUME(ml)	HB/PCV	GROUP	RESEC.TIME(mt)	RESEC.TISSUE(gm)	MVD-SUBURETHRAL	MVD-HYPERPLASTIC PORTION	POST OP HB/PCV	CLOT RETENTION	TRANSFUSION	FAILURE TO VOID	UTI
1	SEBASTIN	71	GR 2	4.2X4.6X4.2	40.57	10.6/32	1	50	30	18.18	16.82	9.6/29	N	N	N	N
2	SANTHANAM	54	GR 2	4.1X4.4X4.0	36.08	10.2/31	1	52	28	17.18	16.34	9.8/30	N	N	N	N
3	VENUGOBAL	78	GR 2	4.4X4.6X4.2	42.53	10.4/32	1	55	30	20.15	15.78	10.2/31	N	N	N	N
4	CHINNAPPAN	65	GR 1	4.4X4.6X4.2	42.53	9.8/30	1	45	22	25.39	16.62	8.2/26	Y	N	N	N
5	KODHANDAN	55	GR 2	4.4X4.6X4.2	42.53	10.1/30	1	50	30	21.89	15.62	9.5/29	N	N	N	N
6	MUDIYAN	60	GR 2	4.3X4.5X4.1	39.67	10.2/31	1	52	29	20.87	15.72	9.7/30	N	N	N	N
7	VELLAI	65	GR 1	3.6X4.8X3.7	31.96	10.5/32	1	45	25	22.57	15.34	9.8/29	N	N	N	N
8	APPADURAI	60	GR1	3.8X4.4X3.7	30.93	10.1/30	1	46	21	21.56	16.56	9.4/28	N	N	Y	N
9	KANNAYIAN	55	GR2	4.1X4.6X4.4	41.49	9.9/30	1	55	30	20.63	17.56	9.6/29	N	N	N	N
10	PADHIRI	75	GR1	4.2X4.6X4.2	41	10.2/31	1	52	20	28.17	16.62	8.6/26	Y	Y	N	Y
11	VEDI	55	GR1	3.7X4.4X3.8	30.93	9.4/29	1	51	24	22.89	15.88	9.2/28	N	N	N	N
12	ARUMUGAM	60	GR2	4.2X4.6X4.4	42.5	10.4/31	1	56	28	21.75	15.8	9.6/29	N	N	N	N
13	SUBRAMANI	52	GR1	3.7X4.5X3.8	31.63	11.2/34	1	47	20	20.89	14.86	10.1/30	N	N	N	N
14	NARASIMMAN	56	GR2	4.2X4.6X4.4	42.5	10.6/31	1	56	26	26.56	15.88	8.4/26	N	Y	N	N
15	SIVAMOORTHY	62	GR2	4.1X4.6X4.3	40.55	11.1/33	1	53	25	22.09	15.24	10.6/31	N	N	N	N
16	SUBBIAH	70	GR1	4.1X4.6X4.4	40	10.2/31	1	55	22	21.67	16.62	9.8/29	N	N	N	Y
17	PERUMAL	73	GR2	4.0X4.5X4.3	46.44	10.4/31	1	48	23	24.12	16.56	9.6/29	Y	N	N	Y
18	PALAYAM	60	GR1	3.6X4.8X3.5	30.24	9.8/29	1	56	20	21.98	17.32	9.5/28	N	N	N	N
19	VENUGOBAL	78	GR2	4.0X4.5X4.3	38.7	10.2/31	1	56	25	21.07	14.56	9.1/27	N	N	N	N
20	KANNAN	72	GR1	4.1X4.6X4.3	41.2	10.6/32	1	52	23	23.1	14.98	9.8/29	N	N	N	N
21	MUNIKRISHNAN	62	GR1	3.9X4.6X3.8	34.08	10.2/31	1	48	24	25.5	15.76	9.4/28	Y	N	Y	N
22	MAHAMANI	65	GR2	4.0X4.4X4.1	36.08	10.8/32	1	56	24	21.85	15.42	9.6/29	N	N	N	N
23	RASAN	65	GR1	4.2X4.6X4.2	41	10.2/30	1	48	18	25.2	15.66	9.6/28	Y	N	N	N
24	KANNAN	77	GR2	4.1X4.8X4.6	46	9.8/29	1	58	24	22.34	16.88	9.6/28	N	N	N	N
25	VELU	70	GR1	4.3X4.8X4.1	43.2	10.2/31	1	55	18	27.45	16.24	8.4/25	Y	Y	N	N
26	THIYAGARAJAN	63	GR1	4.3X4.5X4.1	39.35	11.2/33	1	56	18	22.16	16.62	10.6/31	N	N	N	N
27	SAMIKANNU	80	GR2	4.3X4.8X4.3	44.32	10.2/30	1	54	24	22.45	15.78	9.2/28	N	N	N	Y
28	ARUMUGAM	60	GR1	3.7X4.5X3.8	31.63	10.4/31	1	48	22	21.79	15.88	9.6/27	N	N	N	N
29	RAMALINGAM	73	GR2	4.2X4.8X4.2	42.36	10.5/31	1	66	28	28.56	16.34	8.5/26	Y	Y	N	N
30	CHOKKALINGAN	70	GR2	4.2X4.8X4.6	46.8	10.2/30	1	58	20	22.57	16.22	9.5/29	N	N	N	N
31	CHELLAYAN	65	GR1	4.3X4.8X4.2	43.5	10.3/31	1	54	24	23.15	15.92	9.6/28	N	N	N	N
32	VEERAN	65	GR2	4.OX4.5X4.1	36.9	10.3/31	1	50	26	27.75	14.88	8.5/26	Y	Y	N	N
33	KATHAVARAYAN	65	GR1	3.7X4.6X3.8	32.33	10.5/32	1	55	20	22.45	14.98	9.8/29	N	N	N	Y
34	BALARAMAN	75	GR2	4.2X4.8X4.4	44	10.4/31	1	54	24	21.87	15.62	9.8/28	N	N	N	N
35	PACHIAPPAN	73	GR2	4.0X4.8X4.1	39.36	10.3/31	1	52	25	21.95	16.73	9.5/28	N	N	N	N
36	LOGANATHAN	74	GR1	4.2X4.6X4.2	41	11.2/33	1	56	20	23.02	17.34	10.2/30	N	N	N	Y
37	ANUMANDHAN	82	GR2	4.2X4.6X4.3	41.54	10.4/31	1	62	34	22.54	17.12	9.6/29	N	N	N	N
38	RAJENDRAN	62	GR2	4.2x4.9x4.8	49.39	10.2/30	1	48	26	26.56	16.64	9.8/28	Y	N	Y	N
39	MANIKKAM	60	GR2	4.0X4.6X4.2	38.64	11.2/34	1	58	25	28.67	15.86	8.8/26	N	Y	N	N
40	JEGANATHAN	65	GR1	3.8X4.6X3.7	32.33	10.5/31	1	64	20	24.12	16.34	9.8/28	Y	N	N	N
41	ANNAPPAN	62	GR2	4.2X4.8X4.2	42.33	10.8/31	1	65	32	25.56	16.88	9.8/28	Y	N	N	Y
42	ETHIRAJAN	85	GR2	4.3X4.8X4.2	43.34	10.3/30	1	68	33	22.43	15.78	9.6/28	N	N	N	N
43	MURUGAREDDY	67	GR1	4.3X4.8X4.2	43.5	10.8/32	1	60	20	28.23	15.92	8.6/26	Y	Y	N	Y
44	KUPPUSAMY	65	GR2	4.1X4.5X4.2	38.74	10.2/30	1	56	28	22.43	16.64	9.8/28	N	N	Y	N
45	ANTHONY	65	GR1	3.8X4.8X3.9	35.56	10.4/31	1	55	20	21.78	16.62	9.7/29	N	N	N	N
46	PEER MOHAMED	58	GR2	4.2X4.8X4.4	44.35	10.5/30	1	65	33	28.76	16.78	8.2/25	N	Y	N	N
47	ARUMUGAM	60	GR1	3.7X4.5X3.7	30.8	10.2/30	1	60	25	22.64	16.44	9.5/28	N	N	N	N
48	PERUMAL	80	GR2	4.2X4.6X4.1	39.66	11.2/33	1	56	24	25.87	15.44	8.6/25	Y	N	Y	N
49	SAKARABANI	45	GR1	3.6X4.4X3.9	30.88	10.6/31	1	60	25	21.76	15.92	9.5/29	N	N	N	N
50	AYYAKANNU	51	GR2	4.2X4.8X4.6	46.37	10.8/32	1	65	35	21.67	15.12	9.8/29	N	N	N	N
51	POORAN	62	GR1	3.7X4.5X3.7	30.8	10.2/30	2	58	25	16.68	14.76	9.8/28	N	N	N	Y
52	MANIKKAM	63	GR2	4.1X4.6X4.3	40.55	10.5/31	2	60	31	24.46	14.68	8.6/26	Y	Y	N	N
53	VARATHARAJAN	63	GR2	4.2X4.8X4.4	44.35	10.2/30	2	56	28	15.68	15.14	9.6/28	N	N	N	N
54	NIRENDARADAS	63	GR2	4.2X4.9X4.5	46.3	10.5/31	2	55	30	14.62	14.96	9.5/29	N	N	N	N
55	MASILAMANI	50	GR2	4.2X4.8X4.6	46.37	10.2/30	2	56	32	26.78	14.42	8.6/26	Y	Y	N	N
56	KATHAVARAYAN	60	GR2	4.5x5.2x4.8	56.16	10.4/31	2	60	40	14.68	14.76	9.6/28	N	N	Y	N
57	MURUGESAN	65	GR2	4.2X4.8X4.4	44.35	10.2/30	2	55	30	15.64	14.14	9.6/28	N	N	N	N
58	ATHIMOOLAM	50	GR2	4.6X5.2X4.7	57.4	11.2/33	2	65	39	14.68	14.88	8.6/26	N	Y	N	N
59	PUSPARAJ	76	GR1	3.9X4.5X3.7	32.46	10.6/31	2	54	22	15.48	15.32	9.6/29	N	N	N	N
60	MURUGAN	65	GR2	4.2X4.8X4.5	45.36	10.5/31	2	65	34	14.58	15.42	9.8/29	N	N	N	N

S NO	Name	AGE	DRE-GRADE	USG PROSTATE(cm)	PROSTATE VOLUME(ml)	HB/PCV	GROUP	RESEC.TIME(mt)	RESEC.TISSUE(gm)	MVD-SUBURETHRAL	MVD-HYPERPLASTIC PORTION	POST OP HB/PCV	CLOT RETENTION	TRANSFUSION	FAILURE TO VOID	UTI
61	SUBBURAYAN	70	GR2	4.3X4.9X4.4	46.35	10.2/30	2	60	33	20.95	15.42	8.5/25	N	Y	N	N
62	SELVARAJ	50	GR2	4.4X4.9X4.6	49.59	10.5/31	2	62	35	14.68	14.88	9.6/28	N	N	N	N
63	MUNUSAMY	65	GR1	3.9X4.5X3.8	33.34	10.2/30	2	55	24	14.38	14.68	9.6/29	N	N	N	N
64	KANDASWAMY	77	GR2	4.2X4.8X4.3	43.34	11.2/33	2	65	32	23.34	15.42	8.4/25	Y	Y	N	N
65	BALAKRISHNAN	65	GR2	4.1X4.6X4.3	40.55	10.8/32	2	58	29	15.68	14.88	9.8/29	N	N	N	N
66	DEVARAJ	74	GR2	4.6x5.4x4.9	60.85	10.3/30	2	48	36	14.68	15.42	9.7/29	N	N	N	N
67	VEMBULI	60	GR2	4.2X4.9X4.4	45.27	10.4/31	2	56	30	13.86	14.44	9.7/29	N	N	N	Y
68	KARUPPAN	70	GR1	3.8X4.6X3.8	33.21	10.3/30	2	55	23	18.68	15.62	9.5/29	Y	N	Y	N
69	CHOKKALINGAN	68	GR1	3.9X4.0X3.9	30.42	10.5/31	2	58	22	15.68	14.48	9.6/28	N	N	N	N
70	AJILU	70	GR2	4.3X4.8X4.5	46.44	11.5/34	2	65	35	16.86	15.34	9.8/29	N	N	N	N
71	GOPAL	67	GR2	4.5X4.9X4.4	48.51	10.7/31	2	62	34	13.68	13.88	9.8/29	N	N	N	N
72	SHANMUGASUNDARAM	72	GR1	3.9X4.2X3.9	31.94	10.1/30	2	48	22	17.64	13.46	9.3/28	Y	N	N	N
73	THIMMARAYAN	70	GR2	4.5X4.8X4.4	47.52	11.3/34	2	65	36	14.68	14.88	10.4/31	N	N	N	Y
74	VARATHARAJAN	63	GR2	4.2X4.8X4.6	46.37	10.8/31	2	53	30	14.34	14.88	9.9/30	N	N	N	N
75	CHINNPILLAI	65	GR1	3.8X4.2X3.8	30.32	10.4/31	2	57	23	13.88	15.22	9.5/29	N	N	N	N
76	GOVINDARAJ	64	GR2	4.8x5.2x4.9	61.15	10.4/31	2	58	38	14.46	14.48	9.8/30	N	N	N	Y
77	RAJAMANI	70	GR2	4.5X4.9X4.7	51.82	10.5/31	2	62	38	13.88	14.68	9.8/30	N	N	N	N
78	MANNANGATTI	81	GR1	3.9X4.2X3.8	31.12	10.2/30	2	48	21	15.62	13.78	9.5/29	Y	N	N	N
79	GOVINDARAJ	64	GR2	4.4X4.8X4.6	48.57	11.3/34	2	63	38	14.34	14.66	9.6/29	N	N	N	N
80	VAIYAPURI	51	GR2	4.5X4.9X4.6	50.71	11.2/33	2	57	40	13.78	15.32	10.8/32	N	N	N	N
81	SELVARAJ	71	GR2	4.4X4.8X4.6	48.57	10.6/31	2	54	34	14.32	14.46	9.6/29	N	N	N	N
82	GOVINDARAJ	64	GR1	3.9X4.3X3.9	32.7	10.3/31	2	53	25	13.68	13.66	9.7/29	N	N	N	N
83	MASILAMANI	56	GR2	4.4X4.8X4.7	49.63	10.8/32	2	60	35	14.46	14.14	9.6/28	N	N	N	N
84	ELUMALAI	65	GR2	4.2X4.7X4.6	45.4	10.5/31	2	54	23	14.64	15.12	9.8/29	N	N	Y	Y
85	VELLAIAPPAN	65	GR2	4.1X4.6X4.4	41.49	10.4/31	2	46	29	13.86	13.86	9.8/29	N	N	N	N
86	SUBRAMANI	78	GR1	3.8X4.4X3.9	32.6	10.2/30	2	50	20	14.56	14.88	9.6/28	N	N	N	N
87	MARIMUTHU	48	GR2	4.2X4.8X4.6	46.36	11.2/33	2	55	32	14.88	13.98	10.2/31	N	N	N	Y
88	AHMED BASHA	61	GR2	4.8x5.4x4.9	63.5	10.8/32	2	50	39	14.56	14.66	10.2/31	N	N	N	N
89	DURAIRAJ	75	GR2	4.OX4.8X4.6	44.16	11.2/33	2	65	33	15.68	14.66	10.5/31	N	N	N	N
90	KULLAPPAN	65	GR2	4.1X4.7X4.4	42.39	10.6/31	2	58	29	15.42	14.46	9.6/28	N	N	N	N
91	CHANDRAN	50	GR1	3.8X4.3X3.9	31.86	10.2/30	2	55	23	14.68	15.62	9.5/28	N	N	N	N
92	MUNUSAMY	60	GR2	4.1X4.6X4.4	41.49	10.4/32	2	54	34	14.62	14.34	9.4/28	N	N	N	N
93	MANIKAM	65	GR1	3.9X4.6X3.9	34.98	10.2/31	2	54	24	13.68	14.78	9.6/29	N	N	N	N
94	DEVARAJ	60	GR2	4.4X4.8X4.5	47.52	10.8/32	2	58	38	13.86	13.98	9.7/29	N	N	N	N
95	SRINIVASAN	72	GR2	4.5X4.8X4.6	49.68	10.7/32	2	56	36	13.4	14.12	9.6/29	N	N	N	N
96	VELAYUTHAM	64	GR2	4.4X4.8X4.6	48.57	10.6/32	2	62	38	13.86	15.14	9.6/29	N	N	N	N
97	KRISHNAMOORTHY	58	GR1	3.8X4.3X3.8	31.04	10.5/32	2	58	23	14.34	14.86	9.8/29	N	N	N	N
98	SUNDARAM	80	GR1	3.9X4.4X4.0	34.32	10.5/31	2	54	25	16.86	14.38	9.6/28	Y	N	N	N
99	KRISHNAN	75	GR1	3.7x4.5x3.9	32.46	10.6/32	2	56	22	14.64	13.68	9.6/28	N	N	N	N
100	GOPAL	78	GR2	4.6X4.9X4.5	50.71	10.8/33	2	62	38	13.68	13.24	10.0/30	N	N	N	N
101	CHOKKALINGAN	65	GR2	4.5X4.9X4.6	50.71	10.7/31	3	58	36	13.46	14.12	9.8/29	N	N	N	N
102	MAHENDRAN	75	GR1	4.0x4.4x4.1	36.08	10.6/31	3	56	26	13.78	14.18	9.8/29	N	N	N	N
103	KASI	68	GR2	4.5X4.9X4.6	50.71	10.8/32	3	62	38	14.64	12.46	9.4/28	N	N	N	N
104	KRISHNAN	65	GR2	4.6X4.9X4.7	52.97	10.9/32	3	60	34	13.66	12.88	9.8/29	N	N	N	N
105	MEENATCHISUNDARAM	66	GR1	3.9X4.9X3.9	37.26	10.5/31	3	56	29	21.56	12.46	8.4/26	Y	N	N	N
106	GOVINDASWAMY	65	GR2	4.5X4.9X4.7	51.82	10.4/31	3	52	35	15.64	14.66	9.5/29	N	N	N	N
107	AROKIYASAMY	69	GR1	3.8X4.4X3.9	32.6	10.6/32	3	54	25	14.44	13.46	9.6/28	N	N	N	N
108	ANNAMALAI	55	GR2	4.8X5.8X4.7	65.42	10.8/33	3	62	42	19.46	18.96	8.8/26	Y	Y	N	Y
109	CHAKKARAIYAH	62	GR1	3.8X4.5X3.6	30.78	10.5/31	3	56	23	14.56	15.64	9.5/29	N	N	N	N
110	APPARAO	75	GR2	4.6X4.9X4.6	51.84	10.8/32	3	62	38	13.66	12.88	9.6/28	N	N	N	N
111	MANNIKAM	75	GR1	3.8X4.4X3.7	30.93	10.6/31	3	56	22	13.88	12.46	9.8/29	N	N	N	N
112	RAJAN	63	GR2	4.7X4.9X4.6	52.97	10.4/32	3	54	37	14.24	13.88	9.8/29	N	N	Y	N
113	KOTHANDARAMAN	85	GR2	4.6X4.9X4.5	50.71	10.7/31	3	49	32	13.66	13.14	9.6/28	N	N	N	N
114	HARIKRISHNAN	60	GR1	3.8X4.4X3.7	30.93	10.6/32	3	48	22	12.24	12.08	9.8/29	N	N	N	N
115	CHANDRAMOHANRAO	65	GR2	4.4X4.9X4.6	49.58	10.8/32	3	56	39	12.14	12.04	9.8/29	N	N	N	N
116	ELUMALAI	63	GR2	4.2X4.7X4.3	42.44	10.7/31	3	55	33	13.24	12.46	9.7/29	N	N	N	N
117	PADMANABHAN	65	GR1	3.7X4.7X3.6	31.3	10.5/31	3	47	22	12.46	12.24	9.7/29	N	N	N	N
118	SINGARAM	78	GR2	4.7X4.9X4.6	52.97	10.6/31	3	56	33	13.24	12.68	9.8/29	N	N	N	N
119	RAJANGAM	60	GR2	4.5X4.9X4.6	50.71	10.2/30	3	55	36	12.86	12.12	9.4/28	N	N	N	N
120	KUPPANPILLAI	70	GR1	3.6X4.6X3.8	31.46	10.3/30	3	54	22	12.26	11.68	9.6/28	N	N	N	N

S NO	Name	AGE	DRE-GRADE	USG PROSTATE(cm)	PROSTATE VOLUME(ml)	HB/PCV	GROUP	RESEC.TIME(mt)	RESEC.TISSUE(gm)	MVD-SUBURETHRAL	MVD-HYPERPLASTIC PORTION	POST OP HB/PCV	CLOT RETENTION	TRANSFUSION	FAILURE TO VOID	UTI
121	LOGANATHAN	80	GR2	4.6X4.8X4.5	49.68	10.2/30	3	55	36	13.26	11.98	9.8/29	N	N	N	N
122	ABDUL SAIT	60	GR2	4.4X4.8X4.7	49.63	10.3/31	3	52	34	12.88	11.88	9.5/29	N	N	N	N
123	RAMAMOORTHI	76	GR1	3.8X4.7X3.8	33.93	10.2/30	3	57	23	13.66	12.44	9.5/27	N	N	N	**Y**
124	VENKATESAN	71	GR1	3.7X4.5X3.9	32.46	10.3/31	3	56	24	12.88	12.24	9.6/28	N	N	N	N
125	SIVARAMAN	62	GR2	4.2X4.9X4.6	47.33	10.3/31	3	54	35	13.44	12.62	9.6/28	N	N	N	N
126	GOVINDARAJ	70	GR2	4.4X4.8X4.5	47.52	10.2/30	3	55	36	12.56	11.78	9.4/28	N	N	N	**Y**
127	PERUMAL	68	GR1	3.6X4.4X3.8	30.09	10.4/31	3	56	20	12.86	11.74	9.6/29	N	N	N	N
128	KUPPAN	70	GR2	4.4X4.8X4.3	45.4	10.5/31	3	54	38	16.88	14.68	8.5/26	N	**Y**	N	N
129	SHANMUGAHAIYA	60	GR1	3.8X4.6X3.6	31.46	10.6/32	3	58	22	13.48	12.76	9.5/29	N	N	N	N
130	BEBUN	65	GR2	4.5X4.9X4.6	50.7	11.4/34	3	56	40	13.78	11.98	10.6/31	N	N	N	N
131	PALAYAM	70	GR2	4.3X4.8X4.4	45.4	11.2/33	3	49	32	14.12	12.56	9.7/29	N	N	N	N
132	VEERAN	65	GR1	3.8X4.7X3.8	33.93	10.8/32	3	47	23	15.88	12.68	9.8/29	**Y**	N	N	N
133	KANDAPPAREDDY	70	GR2	4.6X4.8X4.4	48.57	11.3/34	3	62	38	13.62	11.56	10.5/31	N	N	N	N
134	LOGANATHAN	50	GR1	3.5X4.5X3.9	30.71	10.6/31	3	46	21	14.42	13.56	9.8/29	N	N	N	N
135	KANNAN	55	GR1	3.6X4.7X3.9	32.99	10.2/30	3	47	23	13.56	11.44	9.5/28	**Y**	N	N	N
136	DURAI	55	GR2	4.5X4.8X4.4	47.52	10.6/31	3	53	34	13.42	12.42	9.7/28	N	N	N	N
137	ELUMALAI	65	GR2	4.6X4.9X4.6	51.84	11.3/33	3	65	40	13.44	11.56	10.5/31	N	N	**Y**	N
138	SUNDARAJ	57	GR1	3.7X4.8X3.8	33.74	11.2/33	3	45	24	15.46	12.46	10.5/31	N	N	N	N
139	BENEDICT ANTONY	64	GR2	4.4X4.9X4.6	49.58	10.7/31	3	58	34	14.48	12.46	9.8/29	N	N	N	N
140	NAYAGAN	76	GR1	3.8X4.7X3.8	33.93	10.2/30	3	48	21	15.66	14.68	9.5/29	N	N	N	N
141	ALGARSWAMY	65	GR2	4.5X4.8X4.9	52.92	10.5/31	3	53	35	14.82	12.68	8.4/25	**Y**	N	N	N
142	VENKATESAN	62	GR1	3.7X4.8X3.9	34.63	10.2/30	3	55	23	13.46	11.88	9.6/28	N	N	N	N
143	GANESAN	55	GR2	4.6X4.9X4.5	50.71	10.7/32	3	65	40	12.44	11.42	9.7/29	N	N	N	N
144	GOPAL	55	GR2	4.3X4.8X4.5	46.44	10.5/31	3	45	36	12.68	11.56	9.8/30	N	N	N	**Y**
145	DHANGARAJ	55	GR1	3.8X4.6X3.9	34.08	10.4/31	3	47	20	13.48	11.88	9.8/29	N	N	N	N
146	GOVINDASWAMY	60	GR1	3.7X4.6X3.9	33.18	10.2/30	3	56	23	13.44	12.24	9.7/29	N	N	N	N
147	KRISHNAN	75	GR2	4.2X4.8X4.3	43.34	11.2/33	3	54	30	12.66	11.86	10.2/30	N	N	N	N
148	RANGANATHAN	68	GR2	4.3X4.6X4.5	44.5	10.8/32	3	58	35	13.84	11.46	9.8/29	N	N	N	N
149	SULAIMAN	65	GR1	3.8X4.6X3.8	33.21	10.5/31	3	57	23	16.86	13.34	8.6/26	N	**Y**	N	N
150	KANNAPERUMAL	66	GR2	4.5X4.8X4.6	49.68	10.2/31	3	60	35	13.98	12.14	9.5/29	**Y**	N	N	N

PATIENT CONSENT FORM

Title of the Project

ROLE OF DUTASTERIDE IN REDUCING THE COMPLICATION OF TRANSURETHRAL RESECTION OF PROSTATE

Institution : **Department of Urology,**
Madras Medical College,
Chennai-600 003.

Name : Date :

Age : IP No :

Sex : Project Patient No :

The details of the study have been provided to me in writing and explained to me in my own language.

I confirm that I have understood the above study and had the opportunity to ask questions.

I understood that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected.

I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

I have been given an information sheet giving details of the study.

I fully consent to participate in the above study regarding Dutrasteride or Finasteride drug intake 2 weeks before and after surgery. Transurethral resection of the prostate surgery (TURP) and to give the prostatic specimen for the investigation.

_____	_____	_____
Name of the Subject	Signature	Date
_____	_____	_____
Name of the Investigator	Signature	Date

INFORMATION SHEET

Title of the Project

ROLE OF DUTASTERIDE IN REDUCING THE COMPLICATION OF TRANSURETHRAL RESECTION OF PROSTATE

- We are conducting a study on "**Role of dutasteride in Reducing the Complication of Transurethral Resection of prostate**" among patients attending Rajiv Gandhi Government General Hospital, Chennai and for that your co-operation may be valuable to su.

- The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

- You have prostate enlargement due to aging that cause urinary tract obstruction. During the Transurethral resection of prostate surgery (TURP) complication like bleeding can occur. To find out the role for Tab.Dutasteride in reducing the TURP complications, I agree to take the Dutasteride or Finasteride tables before and after surgery and to send the prostatic resected specimen for the investigation.

Signature of Investigator **Signature of Participant**

Date : Date :

<u>தகவல் படிவம்</u>

ஆய்வு செய்யப்படும் தலைப்பு

"சுக்கிய சுரப்பியின் (ப்ராஸ்ட்டேட்) சிறுநீரகத்தாரை வழியிலான அறுவைசிகிச்சையின் பின்பக்கவிளைவுகளை குறைப்பதில் டியுட்ரசைடு பங்குபற்றிய ஆய்வு"

ஆய்வாளரின் பெயர் :
பங்கேற்பாளரின் பெயர் :
ஆராய்ச்சி நிலையம் : சிறுநீரியல் துறை,
சென்னை மருத்துவக் கல்லூரி மற்றும்
ராஜீவ் காந்தி அரசு பொது மருத்துவமனை, சென்னை.

தங்களுக்கு சுக்கிய சுரப்பியில் (ப்ராஸ்ட்டேட்) வயது முதிர்வின் காரணமாக வீக்கம் ஏற்பட்டு சிறுநீர் வெளியேறுவதற்கு அடைப்பு ஏற்பட்டுள்ளது. சுக்கிய சுரப்பியில் சிறுநீரகத்தாரை வழியிலான அறுவைச் சிகிச்சையின்போது இரத்தகசிவு மற்றும் பின்பக்கவிளைவுகள் ஏற்படவாய்ப்புள்ளது. அந்த இரத்த கசிவு மற்றும் பின்பக்கவிளைவுகளை குறைப்பதற்கு டியுட்ரசைடு மருந்தின் பங்குபற்றி ஆராய்ச்சி செய்யவேண்டியுள்ளது. எனவே டியுட்ரசைடு (அ) பினஸ்ட்ரைடு மருந்தை அறுவைசிகிச்சைக்கு இரண்டு வாரத்திற்கு முன்னும் பின்னும் எடுத்துக் கொள்ளவும், சிறுநீரகத்தாரை வழியிலான அறுவைசிகிச்சைக்கும் மற்றும் அறுவைசிகிச்சையின் போது சுக்கிய சுரப்பியின் சதையை ஆய்விற்கு தருவதற்கும் நான் சம்மதம் தெரிவித்துக் கொள்கிறேன்.

முடிவுகளை அல்லது கருத்துகளை வெளியிடும்போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த சிறப்பு பரிசோதனைகளின் முடிவுகளையும் நோயின் தன்மை பற்றியும் ஆராய்ச்சியின்போது அல்லது ஆராய்ச்சியின் முடிவின் போது தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சின்போது தங்களுக்கு எந்தவித பக்கவிளைவுகள் ஏற்படாது என்றும் தெரிவித்துக் கொள்கிறோம். அதையும் மீறி ஏற்படும் சிறு சிறு பக்கவிளைவுகளுக்கு தகுந்த சிறப்பு சிகிச்சை இங்கு அளிக்கப்படும் என்று தெரிவித்துக் கொள்கிறோம்.

பங்கேற்பவரின் கையொப்பம் ..... இடம்..... தேதி.....

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் ..... இடம்..... தேதி.....

ஆய்வாளரின் பெயர் .....

<u>ஆராய்ச்சி ஒப்புதல் படிவம்</u>

<u>ஆராய்ச்சி தலைப்பு</u>

சுக்கிய சுரப்பியின் (ப்ராஸ்ட்டேட்) சிறுநீரகத்தாரை வழியிலான அறுவைசிகிச்சையின் பின்பக்கவிளைவுகளை குறைப்பதில் டியுட்ரசைடு பங்குபற்றிய ஆய்வு

ஆராய்ச்சி நிலையம் : **சிறுநீரியல் துறை,** சென்னை மருத்துவக் கல்லூரி, ராஜீவ்காந்தி அரசு பொதுமருத்துவமனை, சென்னை-600 003.

பெயர் : வயது :

ஆராய்ச்சி சேர்க்கை எண் : தேதி :

பங்கு பெறுபவர் இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது. ☐

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன். ☐

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். ☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கின்றேன். ☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன் 'இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிகிறேன். எனது உடல்நலம் பாதிக்கப்பட்டாலோ அல்லது வழக்கத்திற்கு மாறான நோய்க்குறி தென்பட்டாலோ உடனை அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என்று உறுதி அளிக்கிறேன். ☐

எனக்கு ஆராய்ச்சிக்காக இரத்தப்பரிசோதனையும், ஸ்கேனும், டியூட்ரசைடு (அ) பினஸ்ட்ரைடு மருந்தை அறுவை சிகிச்சைக்கு 2 வாரத்திற்கு முன்னும் பின்னும், சிறுநீரகத்தாரை வழியிலான அறுவை சிகிச்சைக்கும், அறுவைச் சிகிச்சையின்போது சுக்கிய சுரப்பியின் சதையை ஆய்விற்கு தருவதற்கும் சம்மதிக்கிறேன். ☐

பங்கேற்பவரின் பெயர் பங்கேற்பவரின் கையொப்பம் (அல்லது) கட்டைவிரல் ரேகை

ஆய்வாளர் பெயர் பங்கேற்பாளர் கையொப்பம்

இடம் தேதி

INTRODUCTION

Prostate is one of the major accessory sex gland of male reproductive system. The prostate is a pyramidal shaped fibromuscular glandular organ and it surrounds the prostatic urethra from the bladder base to the external urethral sphincter.The prostate was initially divided into five anatomical lobes in fetal life before the 20 weeks of gestation and it has anterior,posterior,2 lateral and middle lobe.In normal adult male only three lobes are present which includes two lateral lobes which can be palpated via the rectum and a median lobe which projects normally into the urethra raising

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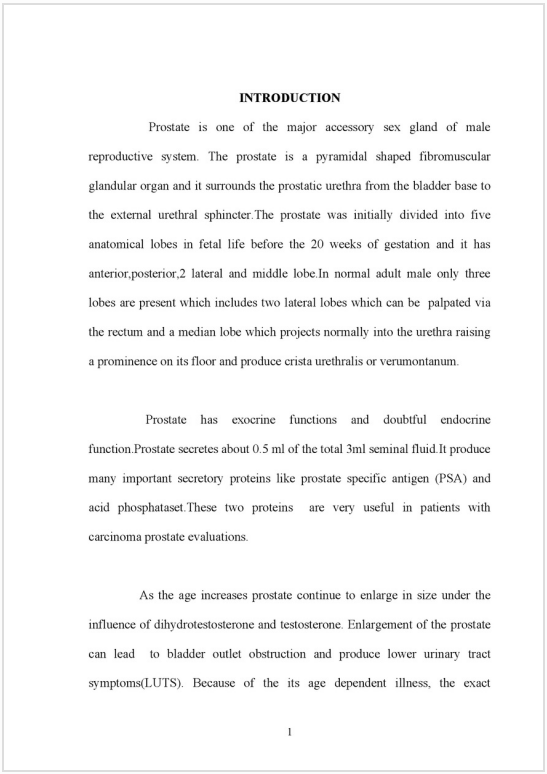

INTRODUCTION

Prostate is one of the major accessory sex gland of male reproductive system. The prostate is a pyramidal shaped fibromuscular glandular organ and it surrounds the prostatic urethra from the bladder base to the external urethral sphincter.The prostate was initially divided into five anatomical lobes in fetal life before the 20 weeks of gestation and it has anterior,posterior,2 lateral and middle lobe.In normal adult male only three lobes are present which includes two lateral lobes which can be palpated via the rectum and a median lobe which projects normally into the urethra raising a prominence on its floor and produce crista urethralis or verumontanum.

Prostate has exocrine functions and doubtful endocrine function.Prostate secretes about 0.5 ml of the total 3ml seminal fluid.It produce many important secretory proteins like prostate specific antigen (PSA) and acid phosphataset.These two proteins are very useful in patients with carcinoma prostate evaluations.

As the age increases prostate continue to enlarge in size under the influence of dihydrotestosterone and testosterone. Enlargement of the prostate can lead to bladder outlet obstruction and produce lower urinary tract symptoms(LUTS). Because of the its age dependent illness, the exact

1